OPTIMIZING FUNCTIONAL AND BIOMECHANICAL OUTCOMES FOLLOWING TOTAL JOINT ARTHROPLASTY

by

Federico Pozzi

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biomechanics and Movement Science

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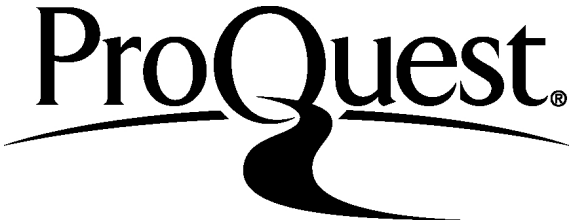

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ABSTRACT

Total joint arthroplasties are common and effective orthopeadic surgery. Patients often experience significant reduction of pain and improvement of perception of function after the surgery. However, patients continue to exhibit biomechanical abnormalities, functional limitations, decreased performance, and reduced activity level compared to older adults without joint pathology.

The overall purpose of this dissertation was to identify optimal rehabilitation strategies to improve outcomes of patients following total joint arthroplasty surgery.

A systematic review of randomized controlled trials was performed to understand optimal rehabilitation treatments for patients after total knee arthroplasty (TKA). Four categories of postoperative treatment strategies were discussed: 1) strengthening exercises; 2) aquatic therapy; 3) balance training; and 4) clinical environment.

A secondary analysis of data from a randomized controlled trial was performed to understand the effectiveness of a progressive strengthening rehabilitation protocol to restore normal physical function after TKA. Data from a control group of older adults without knee pathology were used to build normality intervals for several outcome measures. The proportion of patients after TKA that met a normality cut-off was then compared between a group of patients who underwent progressive strengthening and standard of care rehabilitation.

A longitudinal study was conducted to understand the recovery of patients in the first 12 months after total hip arthroplasty (THA). Recovery was evaluated using a

comprehensive set of outcomes, including self-reported measures of function, impairment based, performance based, and biomechanical measures. Predictors of performance at 12 months were also evaluated to understand impairments associated with optimal recovery.

The feasibility and preliminary effectiveness of a behavioral and exercise intervention for patients 3 to 9 months following THA was then evaluated. The intervention included meetings with a health coach to discuss healthy lifestyle habit, barriers to exercise, and strategies to stay engaged in physical activity. Additionally, patients took part in 18 supervised exercise sessions over the course of six weeks that included two aerobic and one strengthening component. Feasibility was evaluated in terms of session attendance and occurrence of adverse effects (i.e., joint pain, swelling, and tenderness) occurrence. Preliminary effectiveness was evaluated using a comprehensive set of outcomes, including self-reported measures of function and physical activities, impairment based, performance based, and biomechanical measures.

The information obtained in this dissertation further support the importance of progressive strengthening and functional training following TKA. These exercises should be progressed as subjects meet clinical milestones to maintain appropriate intensity. A greater proportion of patients enrolled in a progressive strengthening rehabilitation protocol reached a level of physical function similar to healthy older adults. Therefore, this type of protocol may be more effective compared to standard rehabilitation protocols.

The recovery of patients after THA is not optimal in terms of functional and biomechanical outcomes. Important weakness of hip abductor strength persisted 12

month after surgery. While biomechanical abnormality in the sagittal plane appear to resolve after surgery, excessive trunk lean and pelvis drop angle persist up to 12 months following the surgery. An aerobic and strengthening intervention is feasible and well tolerated in patients at least 3 months following THA. The intervention is effective in improving physical activity and may promote return to higher level of recreational and sport activities. Although hip abductor strength increased at the end of the intervention, weakness in the surgical side persisted compared to the non-surgical side. Biomechanical changes were more variable between subjects. Trend toward greater hip flexion angle and internal flexion moment were seen, and may suggest better dynamic hip joint function.

Chapter 1

EXERCISE THERAPY AFTER TOTAL KNEE ARTHROPLASTY: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

Introduction

Total knee arthroplasty (TKA) is the gold standard treatment for end-stage knee osteoarthritis (OA) and the annual worldwide incidence of TKA has steadily increased over the past decade.[1–3] Data from 21 European countries revealed that the annual incidence of TKA is 109 TKA procedures per 100,000 persons, which is more than twice that reported in 1998.[4] TKA reliably reduces the pain associated with end-stage knee OA and 90% of patients report reduced pain, improved functional ability, and greater health related quality of life after surgery.[5] Moreover, 85% of patients who undergo TKA report being satisfied with the outcomes.[5]

Despite the well documented success of this procedure, patients after TKA continue to demonstrate functional, strength, and mobility deficits after TKA. One year after surgery, women take nearly twice as long to ascend and descend a flight of stairs and are 30% weaker than women without knee pathology.[6] These differences are even larger for men.[6] Although TKA improves self-reported functional ability and reduces pain, it does not eliminate all impairments when compared to age-matched individuals without knee pathology. These residual impairments may also increase the aggregate socio-economic burden of the disease as the demographics of this population shift to a younger working age.[7,8]

Short- and long-term outcomes after TKA may be related to the type and intensity of post-operative rehabilitation the patients receive, although evidence supporting this relationship has been sparse. In 2003, the National Institute of Health convened a consensus development conference to compile the scientific evidence surrounding TKA to enhance guidelines for clinical decision making and patient clinical outcomes. One of the primary conclusions from this consensus conference was that, "the use of rehabilitation services was one of the most understudied aspects of the perioperative management of patients following total knee replacement", and, "there is no evidence supporting the generalized use of any specific preoperative or postoperative rehabilitation interventions."[5]

Persistent functional deficits and muscle impairments after TKA may be partially attributed to ineffective or absent post-operative rehabilitation and exercise programs. Currently, there is no universally accepted rehabilitation protocol for patients after TKA and rehabilitation paradigms are often institution- or surgeon-specific. A recent analysis of standard post-operative care revealed that only 26% of patients receive outpatient physical therapy after being discharged from the hospital.[9] This is disconcerting given that recent evidence has suggested that the type of post-operative rehabilitation influences short- and long-term functional outcomes.[10–12]

Given the potential positive influence of post-operative rehabilitation and the lack of established standards for prescribing exercise paradigms after TKA, the purpose of this study was to systematically review randomized, controlled studies to determine the effectiveness of post-operative outpatient care on short- and long-term functional recovery. This review specifically intended to answer the following

questions: 1) What are the most effective components of outpatient rehabilitation after TKA, and 2) What is the optimal setting to deliver outpatient physical therapy?

Methods

Search Strategy

Five computer databases (Medline, Embase, Cinahl, Cochrane Library, and PEDro) were searched for pertinent articles that were published or available online between January 1, 2003 and June 13, 2013. Database specific search strategies were performed using heading mapping (Appendix 1). Each search included terms such as exercise, physical therapy, physiotherapy, rehabilitation, knee, knee arthroplasty. The results of each search were first imported to a computer-based reference software (EndnoteX, Thomson Reuters) to screen for duplicate studies. Two independent reviewers screened each title and abstract to determine whether the study was eligible for further review. If the two reviewers agreed about the inclusion of a study, the study was included in the next step of review. If the two reviewers disagreed about the inclusion of a study, a third reviewer made the final decision regarding the inclusion/exclusion of the study.

Selection criteria

Publications were eligible if they: 1) examined the postoperative effects of an exercise-based intervention in a non-acute care setting; 2) included pain, physical function, self-reported functional ability, range of motion and/or performance-based test as outcome measures; 3) included participants who underwent unilateral TKA; 4) included a randomized design comparing an exercise-based intervention with a comparative group; and 5) the full report was published in English. An exercise-based

intervention was operationally defined using the definition proposed by Gill&McBurney:[13] "…an intervention that involved participants completing more than one session of physical exercises such as strengthening, flexibility, and/or aerobic activities." Studies that assessed the use of continuous passive motion or compared supervised home therapy versus unsupervised home therapy were excluded from this review. Studies that were conducted solely in an acute care setting were also excluded from the final review. Studies designed to specifically test the efficacy of neuromuscular electrical stimulation (NMES; i.e., intervention group treatment: NMES + conventional physical therapy vs. control group treatment: conventional physical therapy) were excluded from the review.

Assessment of methodological quality

Each reviewer assessed the methodological quality of the included study independently using the PEDro criteria.[14] Results were compared and discrepancies were discussed using PEDro operational definitions to reach agreement. Interpretation of the PEDro score was as follows: score greater than 9, excellent methodological quality; score between 6 and 8, good methodological quality; score between 4 and 5, fair methodological quality; and score lower than 4, poor methodological quality.

Results

Included and excluded studies

Thirty studies were identified as highly relevant for the review. After further screening, 11 studies were excluded because they did not satisfy inclusion criteria (5 evaluated acute-care interventions, 3 focused on NMES, one evaluated home-based exercise versus no exercise, one was not a peer-reviewed publication, and one was not

found in full text version). The characteristics of the included studies and interventions are summarized in table 1. Studies were subdivided into separate categories for discussion including: 1) Strengthening Exercises, 2) Aquatic Therapy, 3) Balance Training, and 4) Clinical Environment.

Table 1 Studies and intervention characteristics.

	Groups	**Program Type**	**Supervised session individual or group**	**Start of program**	**End of program**	**Session duration**	**Frequency**	**Intensity**	**Primasy measures**	**Secondary measures**	**Last follow-up**
Evgeniadis et al. 2008	Intervention	Strengthening lower extremities	Home supervised	After discharge	8 weeks	Unknown	Unknown	Unknown	ILAS	AROM	14 weeks
	Control	No outpatiet therapy		Unknown	Unknown						
Fung et al. 2012	Intervention	Strengthening exercise + 15 min of	Individual	Average 37 day after surgery	Average 54 days	60 minutes	Unknown	Exercised progressed	ROM; 2-minutes walk test; NPR		Unknown

		Wii-Fit game							S; LEFS; ABCS; LOR.		
	Control	Strengthening exercise + 15 min additional lower leg strengthening		Average 46 day after surgery	Average 53 days						
Harmer et al. 2009	Intervention	Water-based dtherapy	Individual	2 weeks post operative	6 weeks	60 minutes	2/week	Exercised progressed	6MW	SCP; WOMAC; VAS pain; ROM	26 weeks
	Control	Land-based therapy	Individual								
Johnson et al. 2010	Intervention	Strengthening exercises on whole body platform	Individual	One month	4 weeks	60 minutes	3/week	Exercised progressed	KISTR; CAR; TUG; VAS-pain; ROM		4 weeks

	Control	Strengthening exercises	Individual								
Kauppila et al. 2010	Interventi on	Multidisciplinary rehabilitation	Group (n=?)	2/4 months post operative	10 days	From 30 to 45 minutes	daily	Unknown	WOMAC	15MT; SCT; AROM; KISTR	12 months
	Control	Usual care	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown			
Kramer et al. 2003	Intervention A	Clinic-based outpatient	Individual	Week 2 post operative	Week 12 post operative	1 hour	2/week	Exercised progressed	KSRS; WOMAC; MOSSF; 6MW; 30SST; AROM		12 months
	Intervention B	Home-based	Phone calls			Unknown	3/day	Unknown			
Levine et al. 2013	Intervention	NEMS + ROM exercise	Home-unsupervised	14 days preoperative	60 days post operative	Unknown	Unknown	Unknown	KSRS; WOMAC; TUG		6 months
	Control	ROM + strengthening exercises	Clinic-based supervised	Unknown	Unknown						

Liao et al. 2013	Intervention	Functional training + balance	Clinic-based supervised	Unknown	8 weeks	60 to 90 minutes	Unknown	Exercised progressed	FRT; SLST; 10MW; TUG; 30SCR; WOMAC		8 weeks
	Control	Functional training				60 minutes					
Liebs et al. 2012	Intervention A	Satandard + aquatic therapy	Clinic-based supervised	6th post operative day	up to 5 weeks	30 minutes	3/week	Unknown	WOMAC	SF-36; LKS	24 months
	Intervention B	Standard + aquatic therapy		14th post operative day							
Madsen et al. 2013	Intervention	Strengthening and endurance exercises + educational sessions	Clinic-based group supervised (n=4 to 8)	4 to 8 weeks post operative	6 weeks	Unknown	2/week	Exercised progressed	OKS; SF-36; EQ-5D	AROM; LEP; TT; 10MW; 30SCR; 5TSS; VAS-pain	6 months

	Control	Endurance, strengthening and fnctional exercises	Home-based	4 weeks post operative	Unknown		Unknown				
Mockford et al. 2008	Intervention	Standard therapy	Clinic-based supervised	Unknown	Unknown	Unknown	Unknown	Unknown	ROM; OKS; BPS; SF-12		12 months
	Control	No outpatiet therapy	Home-unsupervised								
Moffet et al. 2004	Intervention	Intensive functional training	Clinic-based supervised	2 months poto perative	6 to 8 weeks	60 to 90 minutes	2/ week	Exercised progressed	6MW	WOMAC; SF-36	12 months
	Control	Usual care	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown			
Petterson et al. 2009	Intervention A	Progressive strengthening	Clinic-based supervised	3/4 weeks post operative	6 weeks	Unknown	2or 3/ weeks	Exercised progressed	KISTR; CAR; TUG; SCT; 6M	SF-36; KOS-ADL; AROM	12 months

	Control	Usual care	Unknown	Unknown	Unknown		Unknown	Unknown	W		
Piva et al. 2010	Intervention	Functional training + balance	Clinic-based supervised	2/4 months post operative	6 weeks	Unknown	2/week	Exercised progressed	WOMAC; LEFS	WS; SLTS; 5TSS	6 months*
	Control	Functional training									
Rajan et al. 2004	Intervention	Outpatient therapy	Clinic-based supervised	Unknown	Unknown	Unknown	Unknown	Unknown	ROM		12 months
	Control	No outpatiet therapy	Unknown								
Russel et al. 2011	Intervention	Outpatient therapy	Home-remotely supervised	1 week post operative	6 weeks	45 minutes	1/week	Unknown	WOMAC	PSFS; SQLU; TUG; VAS-pain	6 weeks
	Control		Clinic-based supervised								
Tousignant et al. 2011	Intervention	Functional training	Home-remotely supervised	Unknown	8 weeks	60 minutes	2/week	Unknown	ROM; BBT; 30SCR	WOMAC; TUG; TinT; SMA	4 months

	Control	Functional training	Home/Clinic supervised		8 weeks	60 minutes	Unknown			F	
Valtonen et al. 2010	Intervention	Outpatient aquatic therapy	Group-based supervised (n=4 to 5)	Average 10 months post operative	12 weeks	60 minutes	2/week	Exercised progressed	WS; SCT; WOMAC; MP; MCSA		12 weeks*
	Control	No intervention	Unknown		Unknown	Unknown	Unknown	Unknown			
Valtonen et al. 2011	Intervention	Outpatient aquatic therapy	Group-based supervised (n=4 to 5)	Average 10 months post operative	12 weeks	60 minutes	2/week	Exercised progressed	WS; SCT; WOMAC; MP; MCSA		12 months*
	Control	No intervention	Unknown		Unknown	Unknown	Unknown	Unknown			
* Time from randomization											

Abbreviation: PCI, physiological cost index; HHS, Hospital of Special Surgery Scale; KRSR, Knee Society Rating Scale; AKS, American Knee Society clinical score; OKS, Oxford Knee Score; SF-36, short form 36; ILAS, Iowa lower extremity scale; AROM, active range of motion; ROM, range of motion; 2MW, two minute walk test; NPRS, numeric pain rating scale; LEFS, lower extremity functional scale; ABCS, activity specific balance confidence scale; LOR, length of outpatient physical therapy; 6MW, six-minutes walk test; SCP, stair climbing power; WOMAC, Western Ontario and McMaster Universities Arthritis Index; VAS, visual analog scale; 15D, Fifteen-dimensional quality of life, 15MT, Fifteen meters test; KISTR, Knee isometric strength; MOSSF, Medical outcome study short form; 30SST, thirty second stair test;

FRT, functional reach test; SLST, single leg stance test; 10MW, Timed ten meters walk; 30SCR, Thirty second chair rise test; LKS, Lequense knee score; EQ-5D, Euro Qol-5Dimension; LEP, leg extensor power; TT, tandem test; 5TSS, Five time sit-to-stand; BPS, Bartlett patellar score; CAR, central activation ration; PSFS, patient specific functional scale; SQLU, Spitzer quality of life uniscale; GRS, global rating scale; SCT, stair climbing test; TUG, timed up-and-go test; BBT, berg balance test; TinT, Tinetti test; SMAF, Functional anatomy measurements system; MP, muscle power; MCSA, muscle cross sectional area.

Methodological quality assessment

Of the 19 studies that were included in this analysis, 3 were ranked as excellent, 12 were ranked as good, 4 were ranked as fair and 0 were ranked as poor using the PEDro classification (table 2). Of the 19 studies, only 7 studies included an *a priori* power analysis.

Table 2 Methodological quality assessment.

	PEDro Criteria											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**TOTAL**
Evgeniadis et al.[16]	1	1	0	1	0	0	0	0	1	1	1	6
Fung et al.[18]	1	1	0	1	0	0	1	1	1	1	0	7
Harmer et al.[30]	1	1	0	1	0	0	0	1	1	1	1	7
Johnson et al.[25]	1	1	0	1	0	0	0	0	1	1	1	6
Kauppila et al.[32]	1	1	1	1	0	0	0	1	1	1	1	8
Kramer et al.[17]	1	1	0	1	0	0	1	0	1	1	1	7
Levine et al.[27]	1	1	0	1	0	0	0	0	1	1	1	6
Liao et al.[19]	1	1	0	1	0	0	1	1	1	1	1	8
Liebs et al.[15]	1	1	1	1	0	0	0	0	1	1	1	7
Madsen et al.[31]	1	1	1	0	0	0	0	0	1	0	0	4
Mockford et al.[23]	0	1	0	1	0	0	0	1	1	1	0	5
Moffet et al.[26]	1	1	0	1	0	0	1	1	1	1	1	8
Petterson et al.[10]	1	1	0	1	0	0	0	0	1	1	1	6

Piva et al.[20]	1	1	1	1	1	0	1	0	1	1	1	9
Rajan et al.[21]	1	1	0	1	0	0	1	1	1	1	1	8
Russel et al.[22]	1	1	1	1	0	0	1	1	1	1	1	9
Tousignant et al.[24]	0	1	0	0	0	0	0	1	1	1	1	5
Valtonen et al.[28]	1	1	1	1	0	0	1	1	1	1	1	9
Valtonen et al.[29]	1	1	1	1	0	0	1	0	1	1	1	8

NOTE: PEDro criteria: 1. Eligibility criteria were specified. 2. Random allocation. 3. Concealed allocation. 4. Baseline similarity between groups. 5. Subject blinding. 6. Therapist blinding. 7. Assessor blinding. 8. Follow-up >85%. 9. Intention-to-treat analysis. 10. Between-group statistical comparisons. 11. Point measures and measures of variability reported. Item scoring: 1 = present, 0 = absent.

Participant characteristics

All studies included patients who were scheduled for unilateral TKA for primary knee OA and the average age across studies ranged from 65 to 73 years (table 3). One study included subjects who underwent either unicompartmental or total knee arthroplasty.[15] Most studies did not clearly state inclusion and exclusion criteria, which varied across studies. One study required KL grade greater than 2 for pre-operative enrollment.[16] One study required preoperative knee ROM greater than or equal to 90 degrees.[17] Most of the studies excluded subjects who had comorbidities, had complications after the surgery, and subjects who were not able to provide consent. Two studies excluded patients with contralateral painful OA.[10,18] Two studies excluded subjects with BMI greater than 40.[10,19] Three studies excluded patients who were not able to walk without assistive devices.[20–22] Two studies did not report information regarding inclusion/exclusion criteria.[23,24]

Table 3 Participants' characteristics.

	Groups	Number of subjects	Total number of subjects lost	Age	Sex (% of female)
Evgeniadis et al.[16]	Intervention¶	24	9	68.6	70%
	Control	24	4	69.4	87%
Fung et al.[18]	Intervention	27	0	68	58%
	Control	23	0	68	42%
Harmer et al.[30]	Intervention	53	4	67.8	57%
	Control	49	2	68.7	57%
Johnson et al.[25]	Intervention	11	3	67	25%
	Control	10	2	68.5	50%
Kauppila et al.[32]	Intervention	44	8	70.7	76%
	Control	42	3	70.6	79%
Kramer et al.[17]	Intervention A	80	15	68.2	59%
	Intervention B	80	22	68.6	55%
Levine et al.[27]	Intervention	35	7	65.1	76%
	Control	35	10	68.1	62%
Liao et al.[19]	Intervention	65	7	71.4	79%
	Control	65	10	72.9	67%
Liebs et al.[15]	Intervention A	87	21	68.5	70%
	Intervention B	98	29	70.9	73%
Madsen et al.[31]	Intervention	40	4	69.9	47%
	Control	40	8	66.2	50%
Mockford et al.[23]	Intervention	75	4	69.4	65%
	Control	75	3	70.9	58%
Moffet et al.[26]	Intervention	38	0	66.7	56%
	Control	39	8	68.7	63%
Petterson et al.[10]	Intervention‡	41	0	65.4	58%
	Control	41	0	65.9	66%
Piva et al.[20]	Intervention	21	3	70	72%
	Control	22	5	67	72%
Rajan et al.[21]	Intervention	56	0	69	64%
	Control	60	0	68	61%

Russel et al.[22]	Intervention	31	1	66.2	Unknown
	Control	34	1	69.6	Unknown
Tousignant et al.[24]	Intervention	24	3	66	Unknown
	Control	24	4	66	Unknown
Valtonen et al.[28]	Intervention	26	1	66.2	Unknown
	Control	24	3	65.7	Unknown
Valtonen et al.[29]	Intervention	26	1	65.8	Unknown
	Control	24	7	66.4	Unknown
¶, Study included a second experimental group that is not included in the current review.					
ǂ, Study included a between intervention comparison that is not included in the current review.					

Strengthening Interventions

Petterson et al. found that the use of a progressive strengthening protocol (with or without NMES) after TKA produced significantly better 12-month outcomes in terms of quadriceps strength (+21%), Timed Up and Go (TUG) and Stair Climbing Test (SCT) times (-24% and -44%, respectively), and distance walked in the Six Minute Walk (6MW) test (+15%) compared to an embedded cohort in their RCT that received "standard rehabilitation" focused on functional trianing.[10] Similarly, a 4-week strengthening protocol using a whole body vibration platform demonstrated significant improvements in quadriceps strength (84%), TUG time (32%), and flexion range of motion (ROM) (16%).[25] However, this protocol did not produce better outcomes than 4 weeks of a traditional progressive resistive exercise protocol. An intensive functional rehabilitation protocol produced better outcomes than a standard rehabilitation protocol 4 months and 6 months after TKA for the 6MW (8.5% difference), the Western Ontario and McMaster Universities Arthritis Index (WOMAC) (10.5% difference), WOMAC pain score (a 10.5% difference), and WOMAC difficulty score (10.5% difference).[26] However, these improvements were

not maintained at the 12-month follow-up. Evgeniadis et al.[16] reported that individuals discharged from an 8-week home supervised strengthening exercise program had significantly greater knee flexion and extension ROM compared to a control group who only received inpatient rehabilitation (flexion, 98.42° and 80.42°; extension, -0.8° and -6.42°, respectively). In contrast with these results, Levine et al.[27] in a non-inferiority trial found that outpatient physical therapy that included ROM and progressive restive exercises did not improve flexion and extension ROM, WOMAC score, or get-up-and-go tests to a greater extent than a protocol that included only NMES and home-based exercises.

Aquatic Therapy

Patients enrolled in a water based exercise program on the 6th postoperative day had on average 5% better WOMAC scores at the 3-, 6-, 12-, 24-month follow-up after TKA compared to patients that started the same program on the 14th postoperative day.[15] These differences were not significant, but the effect size ranged from 0.22 at the 6-month follow-up to 0.39 at the 24-month follow-up. Valtonen et al.[28] reported significantly better knee flexion (36%) and extension (30%) power, habitual walking speed (8%), and stair climbing time (14%) in subjects who underwent 12-weeks of a water based resistance exercise program compared to subjects who did not receive any intervention (participants were instructed to maintain their usual level of activity). However, only knee extensor and flexor power remained significantly different between groups 12-months after TKA.[29] In a study that compared a 6-week aquatic program to 6 weeks of land-based therapy,[30] there were no group differences for 6MW, stair climbing power, WOMAC score, or knee flexion and extension ROM.

Balance Training

Piva et al.[20] found that 6-weeks of balance specific training in addition to an intensive functional rehabilitation protocol produced increased self-selected gait speed by 8% and single leg stance time by 24% compared to baseline. The control group demonstrated 1% reduction in gait speed and 6% decrease in single leg stance time, although significance between groups was not assessed in this study. Similarly, Liao et al.[19] found that subjects enrolled in an 8-week balance specific rehabilitation protocol had significantly better single leg stance times (20%) and faster gait speeds in the 10-meter walk test (18%) compared to subjects enrolled in intensive functional rehabilitation that did not include balance retraining. Moreover, subjects in the experimental group had also better WOMAC scores (13%), longer functional reach (31%), and took less time to complete the TUG and the SCT (both 9% difference). In contrast to these findings, Fung et al.[18] reported that the addition of 15 minutes of balance specific exercises executed on a Wii-Fit® Balance Board to standard physical therapy did not produce better outcomes in terms of knee flexion and extension range of motion, the two minute walk test, the activity specific balance confidence scale, lower extremity functional scale compared to adding 15 minutes of conventional strength and balance training.

Clinical Settings

Rajan et al.[21] and Mockford et al.[23] reported that subjects enrolled in standard outpatient physical therapy achieved similar ROM 12 months after TKA compared to subjects who were not enrolled in outpatient physical therapy. Furthermore, Mockford et al.[23] did not find differences between groups for the Oxford Knee Score, Bartlett patellar score and SF-12 score 12 months after TKA. Other authors have found that

home-based and clinic-based rehabilitation protocols generated similar improvements in WOMAC score, knee rating scale, 30-second stair test, 6MW, and knee flexion room 12 weeks and 12 months following TKA.[17] No differences were found between ROM, leg extensor power, 30-second sit to stand repetition, walking velocity, and self-reported measure of function for a group who attended group-based outpatient rehabilitation and one who followed a home-based rehabilitation program.[31]

Similarly, subjects enrolled in a telerehabilitation program that was remotely supervised by a physical therapist obtained similar improvements in WOMAC,[22,24] knee ROM,[22,24] Berg balance scale,[24] 30-second chair rise test,[24] TUG,[22,24] and the Tinetti test[24] compared to a group that attended standard rehabilitation. These results were maintained 4 months after discharge from physical therapy.[24] Kaupilla et al.[32] reported that subjects enrolled in a 10 day multidisciplinary rehabilitation program after primary TKA did not attain faster recovery or better outcomes compared to subjects enrolled in standard rehabilitation. These authors found that both treatments were effective at improving scores on the WOMAC, 15-meters walk test, SCT, peak knee extension torque, and knee ROM compared to pre-operative values.

Discussion

Strengthening Interventions

Although quadriceps weakness is a hallmark characteristic of OA, there is a precipitous decline in strength the first few weeks after surgery.[33–35] This is a direct consequence of the surgical procedure, immobilization, atrophy and primarily neuromuscular inhibition.[36,37] Quadriceps strength predicts 28, 26, and 37% of the variability in the TUG, SCT, and 6MW tests respectively, indicating that quadriceps

strength is the stronger predictor of functional performance following TKA.[10] Therefore, it is imperative to address quadriceps strength deficits following TKA.

This was highlighted in the report by Petterson et al.[10] who compared outcomes of progressive strengthening protocols (with or without NMES) to an embedded cohort of individuals (standard of care group) who did not receive progressive strengthening after TKA. One year after TKA, subjects enrolled in either progressive strengthening group (with or without NMES) had significantly higher quadriceps strength and better performance-based test results (TUG, SCT, 6MW) compared to a group that was enrolled in standard care. ROM in subjects in both progressive strengthening arms was excellent and three months after TKA, subjects had 115 degrees of knee flexion and nearly full extension. TUG times were approximately 8 seconds. There was no difference between progressive strengthening and standard of care groups in self-reported functional ability or knee ROM, suggesting that self-reported measures capture different domains of disability than do performance-based tests. This discrepancy has been substantiated by several others who have found that performance-based tests are driven by muscle strength and self-report questionnaires are driven by pain.[38–42]

Johnson et al.[25] assessed the effectiveness of using whole body vibration as a means of administering general lower extremity strengthening exercises. The control group received progressive strengthening exercises based on the protocol published by Stevens et al.,[43] while the experimental group received progressive strengthening exercises using a whole body vibration platform. To ensure progression, exercise and vibration amplitude and duration were systematically increased. Similar improvements of extensor strength, pain level, and TUG time were found between groups after 4

weeks of treatment and subjects in the experimental group did not report any adverse effect of vibration exercises. TUG times were near age-matched values and were similar between groups 7 to 10 weeks after TKA (7.8 s in the vibration group and 8.8 s in the exercise group). The vibration group had 116 degrees of total range of knee motion, which was 10 degrees more than the exercise group, but neither group demonstrated significant improvements relative to pre-operative values. The authors suggest that whole body vibration may provide a valid alternative to traditional strengthening exercises after TKA, but these findings must be substantiated in larger trials with longer-term follow-up. The accuracy of equivocal (or non-superior) findings from a study with such a small sample size (16 subjects), no long-term follow-up, and no *a priori* power analyses is questionable until corroborated by additional evidence.

Moffet et al.[26] developed a rehabilitation protocol for patients after TKA based on the motor learning and training-specificity principles called intensive functional rehabilitation (IFR). The protocol involved 12 therapist-supervised sessions (duration of 60-90 minutes) with individualized home exercises executed on the days without supervised treatment. The IFR included a warm-up, specific strengthening exercises, functional task-oriented exercises, endurance exercises, and cool-down period. Seventy-seven subjects were randomized to either receive IFR or usual care. The authors did not control what "usual care" the control group received, but did collect that information. The authors only reported that 10 subjects in the control group received home rehabilitation services after TKA, but did not describe the exercises or progression that occurred in that group. Four to six months after TKA, subjects randomized to receive IFR had greater improvements in the total WOMAC score and

the WOMAC pain score, as well as walked a further distance during the 6MW compared to the control group. One year after surgery, there were no significant differences between the groups and only 43.5% of subjects (30 of 69) had 6MW distances that were within normal ranges. Of those 30 subjects with normal 6MW values, 20 were in the IFR group.

Evgeniadis et al.[16] randomized 72 patients in three groups of 24 subjects each. All subjects were enrolled in standard inpatient rehabilitation that lasted 12-14 days, but one group underwent a home-based exercise program for three weeks prior to surgery that focused on strengthening the trunk and upper body. The control group received no additional therapy, while the third group underwent eight weeks of home-supervised exercises to strengthen the lower extremity. Active ROM of the knee and functional ability (measured using the Iowa Level of Assistance Scale) were collected during the 10^{th} and 14^{th} weeks after the surgery. Ten weeks after surgery, patients enrolled in the postoperative exercise program presented with greater range of motion (both flexion and extension) and better functional ability compared to the preoperative exercise and control groups. Fourteen weeks after surgery, the postoperative exercise group had significantly greater knee ROM compared to the other two groups. At this time point, knee ROM values were: 80.42 and -6.42° for the control group; 80.73 and -5.7° for the preoperative exercise group; 98.42 and -0.8° for the postoperative exercise group. The authors concluded that only a postoperative exercise program is effective at restoring knee ROM after surgery, although no group in this study averaged more than 100 degrees of knee flexion 14 weeks after TKA.

In a non-inferiority randomized trial of 70 subjects, Levine et al.[27] evaluated the effect of NMES on range of motion, WOMAC scores, and Get Up and Go times.

Subjects were randomized to receive supervised physical therapy that included range of motion (ROM) and strengthening exercises or home-based treatment that included NMES and ROM exercises. NMES treatment started 14 days preoperatively and lasted until 60 days postoperatively with no NMES the day before or after surgery. These authors found no differences between groups for ROM, self-reported functional ability (WOMAC) and TUG times and concluded that home exercises with NMES, "may provide an option for simplifying and reducing cost of the postoperative TKA recovery process without compromising quadriceps strength or patient satisfaction." However, the authors did not provide a detailed description of either rehabilitation protocol and there was no information on dose, duration, or frequency of treatments. No cost analysis was performed. Six months following surgery, the Get Up and Go times of both the experimental and control groups were 10.64 and 10.25s, respectively. These values were greater (took longer to complete the task) than other published reports examining NMES. At the same time point, the experimental and control groups of the study by Stevens-Lapsley et al.[11] completed the task in 7.1 and 8.8 s, respectively. Experimental and control groups of the study of Petterson et al.[10] reached better values 3 months following TKA (8.29 and 8.02 s). These slower times from the subjects by Levine et al.[27] suggest that subjects in this study were under-rehabilitated. Quadriceps strength, the impairment targeted by NMES, was not evaluated.

Post-operative, progressive exercise programs improve outcomes to a greater extent than post-operative care that does not include elements of muscle strengthening. The results from both randomized arms of the study by Petterson et al.[10] produced excellent range of motion and TUG times within 3 months of TKA. Subjects in the

study by Moffet et al.[26] had better WOMAC scores and 6MW distances, with the majority of subjects in the exercise group achieving normal 6MW distances one year after TKA. Although subjects in exercise group in the study by Evgeniadis et al.[16] had better outcomes then a control group, mean knee flexion in the post-operative exercise group was still less than 100 degrees. The range of motion results in the other two groups that did not receive post-operative strengthening exercise were extremely low with knee flexion range of motion of ~80 degrees and substantial knee flexion contractures (lacking ~6 degrees of extension). Although the post-operative group was supervised, it was performed at home. It is possible that the poor outcomes in the exercise group are a consequence of the environment in which the rehabilitation was performed. Without use of resistive equipment and modalities that are commonplace in a physical therapy facility, at-home exercise programs may not provide optimal outcomes. The studies by Petterson et al.[10] and Moffett et al.[26] were performed in a rehabilitation clinic and this may be related to the substantially better outcomes found in these two studies compared with the outcomes reported by Evgeniadis et al.[16] Collectively, the findings from these studies on exercise suggest that not only should post-operative strengthening exercises be a primary component of post-operative care, but the exercise programs should be supervised and progressed as the patients meet clinical and strength milestones.

Aquatic Therapy

Proponents of water-based rehabilitation protocols argue that exercising in warm water may reduce the stress on the joint and allow the individual to strengthen their lower extremities using water as resistance while taking advantage of the weight reducing effects of buoyancy. However, water-based rehabilitation may increase the

per-session cost and there have been few cost-effectiveness or comparative effectiveness studies assessing aquatic therapy in a post-surgical TKA population.

Using principles of buoyancy may be most effective in the early stages after TKA when pain or muscle impairments limit the ability to perform resistance exercises in weight bearing positions. Liebs et al.[15] found that water-based therapy can be safely started as early 6 days after TKA as long as the wound is covered with a waterproof adhesive dressing. These authors also revealed that subjects randomized to start water-based therapy on the 6th post-operative day had better WOMAC, SF-36, and Lequense Knee scores 12 and 24 months after TKA compared to subjects who were randomized to start aquatic therapy on the 14th postoperative day. While these results were not statistically different between groups, the effect size of the intervention on WOMAC score (range 0.22 at 6 months to 0.39 at 24 months) was similar to the effect of nonsteroidal anti-inflammatory drugs on functional limitations associated with knee OA. The change in WOMAC score also exceeded the minimal clinical important difference cut-off 24 months following surgery. However, these authors used only self-reported measure of function and did not compare the outcomes of aquatic based therapy to other land-based rehabilitation paradigms.

Valtonen et al.[28] analyzed the effect of a water-based resistance training program on mobility limitations (walking speed and stair ascent time), self-reported function (WOMAC), and lower-extremity strength (isokinetic power and quadriceps cross sectional area). Fifty subjects were randomized to either an aquatic program in which progressive strengthening exercises were performed in the pool or were advised to maintain their usual physical activity level. Intensity of the treatment was also estimated in 6 subjects (3 male and 3 female) using the Rate of Perceived Exertion

(RPE) scale (0 = no effort; 20 = maximal effort) and a heart rate monitor. Over the 12 weeks of training, the average RPE value was 17 and the average heart rate was 116 (73% of the heart rate maximal for those subjects), which suggest that training intensity was high. At the end 12 weeks of training, subjects in the experimental group had better knee flexion and extension power, greater cross sectional area, faster self-selected walking speed, and faster stair ascent time compared to control subjects. No differences were found for WOMAC score. Twelve months after the surgery, the knee extensor and flexor powers were still 32 and 48% higher, respectively, in the experimental group compared to control group. No differences between groups were detected in relation to cross sectional area, walking speed, and stair ascent time at the one year follow-up.[29] These findings lend evidence to the benefit of high-intensity and progressive exercises performed on land or in water, although the subject sample was comprised of subjects in the late stages of recovery after TKA (average 10 months post-operative). This exercise program may expedite recovery and be more advantageous to subjects early after TKA; future work should be conducted to explore this possibility.

In contrast, Harmer et al.[30] randomized 102 patients scheduled for TKA to receive either land-based or water-based physical therapy. Both groups attended therapy twice a week for 6 weeks and each session lasted for 60 minutes. The same therapist supervised both water- and land-based treatment and the exercise prescription was highly standardized to ensure that the only difference between treatment groups was the medium (water versus land). Subjects were evaluated 8 and 26 weeks after TKA and there were no differences between groups for WOMAC score, knee range of motion, 6MW, and stair climbing power, although both groups

demonstrated significant improvement compared to baseline. The authors concluded that water-based therapy was not particularly advantageous with respect to functional outcome or clinical metrics, although it may be a valid alternative treatment for rehabilitation after TKA.

Balance training

Balance is a critical impairment in patients with TKA and persistent muscle weakness. Patients after TKA are at a higher risk for falling and further orthopaedic injury.[44,45] Resolving balance impairments after TKA should be an important goal of physical therapy. Two studies with similar methodology assessed the effectiveness of adding specific balance exercises (agility and perturbation drills) to an IFR protocol. Piva et al.[20] found that subjects who were randomized to receive 6 weeks of balance training had faster self-selected walking speed and performed better on a single leg stance test for unilateral balance than subject randomized to receive only the IFR protocol. Both groups in this study demonstrated similar improvements in the WOMAC and 30 second chair rise test. However, only confidence intervals were reported and tests of significance were not performed in this study. Liao at al.[19] found that the addition of balance exercises to a post-operative rehabilitation program significantly improved functional forward reach, single leg stance, sit-to-stand test, stair climbing time, 10 meter walk time, TUG scores, and the WOMAC to a greater extent than a control group that did not receive balance retraining exercises. It should be noted that Liao et al.[19] had a larger sample size (130 versus 43) and longer intervention (8 versus 6 weeks) than the study by Piva et al.[20] Additionally, subjects randomized to receive balance retraining in the study by Liao et al. also had a longer duration session than subjects in the control group in the same study (“up to” 90

minutes versus 60 minutes). Considering a twice per week physical therapy plan of care, the 30 additional minutes of therapy at each session increased total treatment time by up to 5 hours.

New interactive technologies have been recently applied to rehabilitation sessions with the aim to increase strength and balance while improving patient stimulation, compliance, and satisfaction with treatment. Fung et al.[18] tested the use of integrating the Wii-Fit® game into a rehabilitation paradigm after TKA. In addition to standard therapy, subjects randomized to the experimental group received 15 minutes of Wii-Fit® gaming activity, while the control group received 15 minutes of additional lower extremity exercise. There were no differences between groups for range of motion, two-minute walk test, numeric pain rating scale, activity-specific balance confidence scale, the lower extremity functional scale, and length of outpatient rehabilitation. These findings suggest that the addition of Wii-Fit® as an alternative to some lower extremity strengthening may be an appropriate rehabilitation tool.

Clinic Environment

Outpatient physical therapy conducted in a clinic-based setting is advantageous in that a physical therapist can directly monitor patient progress and modify the intervention with changes in the patient's functional status. However, physical therapy conducted in an outpatient clinic is more expensive than home exercises and requires that the patient travel to the clinic, which may be difficult for the elderly population. Therefore, it is important to determine if supervised outpatient rehabilitation is superior to no standardized care, home-based rehabilitation (with phone call monitoring), and/or telerehabilitation (where the patient is supervised remotely by a therapist).

Rajan et al.[21] randomized 116 to receive either inpatient therapy or inpatient plus outpatient therapy. However, the dose, frequency and intensity of outpatient therapy were not quantified in this study and subjects were excluded if they used an assistive device to walk. The authors only state that "outpatient physiotherapy is usually given, on average, 4–6 times after discharge from hospital," which is considerably less than the outpatient sessions reported in other randomized trials.[10,12,19,20] Although outpatient physical therapy typically provides strengthening, stretching, and functional retraining exercises, only knee ROM was assessed in this study. In the group that received outpatient therapy, the knee range of motion was 92° at baseline and increased to 95, 97 and 98° during the 3, 6, 12 months follow-up. Similarly, in the group that did not receive outpatient therapy, the range of motion was 90° at baseline and increased to 92, 93 and 96° during the follow-up evaluations. Based on these numbers, no differences of knee ROM were found between groups 3, 6, and 12 months after TKA, although neither group had achieved mean flexion ROM that exceed 100°.

Similarly, Mockford et al.[23] randomized 143 patients in two groups: one received outpatient therapy, the other only received inpatient therapy. Minimal information regarding the inpatient treatment was provided and it was reported to start on postoperative day 1 and include functional and strengthening exercises. No detailed information was given regarding the dose, frequency or intensity of the outpatient therapy and this treatment arm was only described as "standard outpatient physiotherapy regime." No differences between groups were found for flexion and extension ROM, Oxford Knee Score, Bartlett Patellar Score, and SF-12 twelve months after surgery. These authors concluded: "a standard routine course of outpatient

physiotherapy does not offer any benefit in the long-term to patients undergoing TKA." However, these authors did not provide information about the inclusion and exclusion criteria that defined their sample.

The conclusions by Rajan et al.[21] that there is "no need for outpatient physiotherapy after total knee arthroplasty" and by Mockford et al.[23] that "a standard routine course of outpatient physiotherapy does not offer any benefit in the long-term to patient undergoing TKA" are not supported by the methodologies and results from these studies. In both studies, there was no standardization or description of the protocol or duration of the outpatient physical therapy intervention and only range of motion and self-reported outcomes were assessed to make determinations about the effectiveness of outpatient rehabilitation. Additionally, one year after surgery, subjects in both studies had knee flexion range of motion (97 and 108 degrees) that was lower than the cutoff for functional range of motion (110 degrees)[46] and less than the 120 degrees reported by Petterson et al.[10] These low knee flexion angles from Rajan et al.[21] and Mockford et al.[23] suggest that neither treatment arm was effective at managing post-operative range of motion impairments.

To determine the effectiveness of home-based therapy monitored via telephone contact, Kramer et al.[17] randomized 160 patients to receive either clinic-based or home-based therapy. Both groups were given two booklets of ROM and strengthening exercises with the prescription to perform them at home three times per week for 12 weeks. A physical therapist familiar with the protocol followed up weekly with the home-based group to monitor adherence and compliance with the protocol. The clinic-based group attended therapy twice a week for 12 weeks for one-hour sessions. At the 12th and 52nd week follow up, values for WOMAC, SF-36, 6MW, 30-second chair test,

knee flexion ROM were significantly better compared to baseline in both groups and there was no relative advantage of one group over the other. Both groups had knee flexion less than 100 degrees at the one year follow-up and 6MW distances were 400 m or less.

Madsen et al.[31] also compared home-based and clinic-based rehabilitation. In this study, 80 patients were randomized to receive either home- or clinic-based rehabilitation. The clinic-based group received 12 group treatment sessions over 6 weeks consisting of: 1) strengthening and endurance training; 2) educational session on TKA relevant topics; and 3) discussion sessions where patients were encouraged to share experiences and discuss the topic of the educational session. The home-based group underwent an initial visit with a physical therapist during which the home-based training was adjusted to each individual needs. Additionally, one to two visits with a physical therapist were then planned during the home-based treatment to further adjust the program. Three and 6 months after TKA, there were no differences between groups after adjusting for baseline values for the self-reported measures (Oxford Knee Score, the physical function part of the SF-36, the EuroQol-5 Dimension), impairment-metrics (leg extension power, pain level during the power test), and performance-metrics (tandem test for balance, 10m walking test, 30s sit-to-stand and five-times sit-to-stand tests). The outcome data from this study were presented as percentage change from baseline, making comparisons to previous work difficult and limiting our interpretation of the effectiveness of either treatment.

Two different studies compared the use of telerehabilitation to conventional outpatient physical therapy.[22,24] A total of 113 patients were randomized to either receive outpatient physical therapy or telerehabilitation, which consisted of a

teleconference system to allow therapist to directly and remotely supervise patients during exercises. Tousignat et al.[24] required a family member or a friend of the patient to undergo a training session and be present during therapy to ensure patient safety. Russell et al.[22] developed a measurement tool, which allowed measurement of performance over the internet and allowed the therapist to obtain high-quality videos of the patient performing the rehabilitation exercises. In both studies the treatment duration and length was balanced between groups. No differences between groups were found for the WOMAC, TUG, and flexion and extension ROM at the end of the treatment and the authors suggest that both outpatient and telerehabilitation are effective treatment after TKA. Despite the lack of between group differences, both groups were under-rehabilitated in the study by Russell et al.[22] On average, subjects in this group had residual knee flexion contractures and were unable to do a straight leg raise without a quadriceps lag, indicating significant residual weakness. Additionally, TUG times in this group were still greater than 12 seconds at the conclusion of the study, nearly 50% longer than the TUG times reported by Petterson et al.[10] 3 months after TKA and the times in the experimental group reported by Stevens-Lapsley et al.[12] only 6.5 weeks after TKA.

The results from the home-therapy and telerehabilitation studies suggest that ROM, strength and functional impairments are not completely resolved with this type of post-operative treatment strategy. Although, home-based or telerehabilitation may be beneficial for subjects who cannot attend clinic sessions or live in remote areas, further studies are need to ascertain whether home-therapy or telerehabilitation can produce similar outcome compared with clinic-based progressive strengthening

protocol or intensive functional training, which requires constant and progressive modification of the treatment based on patients' specific progression and needs.

Kauppila et al.[32] tested whether a 10-day multidisciplinary rehabilitation program was effective in achieving faster and greater functional recovery after TKA. Subjects in the experimental group attended the multidisciplinary program 2 to 4 months after the surgery. This program involved completing group exercises sessions with a physical therapist and attending lectures from a variety of health care personnel (orthopaedic surgeon, psychologist, and nutritionist). The control group followed usual care. The results of this study showed that this intervention did not improve outcomes or achieved faster recovery after TKA. However, subjects who undergo TKA often have comorbidities including depression, obesity, and cardiovascular impairments, and may benefit from a multidisciplinary rehabilitation treatment after the surgery. Future studies are needed to test this hypothesis.

Recommendations for Treatment and Future Studies

Based on the results from this review, the optimal outpatient physical therapy protocol should include: strengthening and intensive functional exercises given through land-based or aquatic programs, that are progressed as the subject meets clinical and strength milestones. Due to the highly individualized characteristics of these types of exercises, outpatient physical therapy performed in a clinic under the supervision of a trained physical therapist may provide the best long-term outcomes after the surgery. If treatment within an outpatient clinic is not feasible, supervised or remotely supervised therapy may be effective at reducing some of the impairments after TKA, although the initial evidence suggests that telerehabilitation does not resolve range of motion, strength and functional impairments to the same extent as

supervised physical therapy sessions that include progressive exercise. Although outside the aim of this review, it is important to highlight that early use (starting from postoperative day 2) of NMES has been suggested to be a necessary treatment to attenuate the early loss of quadriceps strength after TKA and optimal protocols may include components not assessed in this review.[12,35–37,47,48]

The trials that suggested that outpatient physical therapy is not necessary after TKA lack methodological controls and subjects in all groups appeared under-rehabilitated.[21,23,27] Moreover, none of these trials provided evidence that home-based[17] or lack of outpatient[21,23,27] care was superior and no metrics were collected with respect to patient safety, cost or long-term outcomes, which must be evaluated before any conclusions as to the necessity of outpatient physical therapy can be made. Therefore, we cannot recommend that post-operative rehabilitation exclude outpatient physical therapy or supervised exercise programs

Although the mean methodological quality was good (6.9), the PEDro ranking does not consider three additional attributes that are essential to determining the quality of the study and evaluating the generalizability and usefulness of the results. First, in any randomized controlled or comparative effectiveness study, an *a priori* sample size is required. This sample size should be based on preliminary data or established clinically important differences for the metric that will be used as the primary outcome. Only 7 of the studies in this review included a sample size justification.

Secondly, exercise and post-operative physical therapy are not standard treatments. Authors cannot simply compare one treatment versus “standard physical therapy” without providing information about the treatment paradigm, dose,

frequency, intensity, criteria for progression, and evidence of progression and compliance within that group. Future studies that wish to evaluate a novel or different outpatient treatment to standard physical therapy should use the best, most effective protocol as the comparison group. These protocols should include at least 12 supervised and progressive strengthening exercises sessions, which should start within the first post-operative month, although starting rehabilitation programs earlier after TKA may produce better outcomes.[11,12] Only when comparisons are made to an optimal treatment we can determine if a different post-operative rehabilitation or exercise strategy is more beneficial. The majority of studies in this review did not include all attributes of the comparative or control groups and both arms (experimental and control) appeared under-rehabilitated with substantial weakness, limited range of motion and functional deficits. Comparison to normative values should be done in all trials to compare not only the effectiveness between treatments, but also the effectiveness of the treatment to restore normal age-matched functional ability.

Finally, the outcome metrics must align with the goals of the intervention and should be related to functional performance. Several authors have concluded that self-reported measures of function are driven mostly by pain, and should not be used in isolation to measure post-operative outcomes.[38–42] Performance-based metrics are required to obtain a complete description of the recovery after TKA. Lower extremity strength, particularly quadriceps strength, is highly related to functional performance and should certainly be included in any intervention that targets muscular impairments after TKA. Although knee range of motion is a concern of most patients and clinicians, this value has little relation to functional performance once at least 110 degrees of flexion are achieved.[46] For studies of OA and TKA, the Osteoarthritis

Research Society International recommends that the 30 second chair rise test, 4x10m fast-paced walk test, a timed stair climbing test, TUG, and 6MW be included as outcome measures.[49]

Most studies in this review also had strict inclusion and exclusion criteria for patient selection and excluded many subjects with co-morbidities. The results from these studies may not be applicable to all patients who undergo TKA, given that many patients with end-stage OA have co-morbid orthopaedic and cardiovascular conditions. Future studies should evaluate a broader TKA cohort.

In conclusion, progressive exercise is critical to recovery after TKA. There is a large decrease in quadriceps strength immediately after TKA, which is attributed to activation deficits and atrophy.[33,37] This loss of strength is related to functional impairments[10,35] and biomechanical asymmetries.[50] Progressive exercise protocols and early application of NMES should be used to attenuate early quadriceps weakness and the associated impairments. Further work is needed to fully elucidate the relationship between post-operative exercise protocols and outcomes, given that most studies did not accurately describe the "usual care" groups that were included as treatment arms in these randomized trials.

Chapter 2

EFFECTIVENESS OF A PROGRESSIVE STRENGTHENING REHABILITATION PROTOCOL TO RESTORE NORMAL KNEE FUNCTION ONE YEAR AFTER TOTAL KNEE ARTHROPLASTY

Introduction

Total knee arthroplasty (TKA) is the gold standard treatment for end-stage knee osteoarthritis.[1] Over 719,000 TKA surgeries are performed annually in the United States,[51] and this number is projected to increase to 3,000,000 by 2020.[3] This increase is due in part to the strong association between age, BMI and OA pathology; the fastest growing class in our population includes people that are 65 or older[52] and obesity rate are spiking among all ages. However, older age and higher BMI cannot entirely justify the increased incidence of TKA in the last 10 years.[7,8] Losina et al.[7] analyzed the relationship between TKA utilization, population growth, and obesity prevalence during the decade from 1999 to 2008. During that decade, TKA incidence increased 134%, which exceeded the 11% increase in the adult population and the 23% increase in obesity. Moreover, the number of TKA procedures performed in individuals between the ages of 45-64 increased from 30% in 1999 to 41% in 2008.[8] In contrast, the number of procedures performed on individuals 65 and older decreased from 68% to 57%. This data suggests that, in addition to aging and obesity, TKA use in younger individuals likely contributed to the increase in incidence of primary TKA.[7]

TKA is an excellent procedure to reduce knee joint pain; therefore, it is not surprising that satisfaction rates with this procedure are high (80%).[5,53] Self-reported measures of function show significant improvement soon after the surgery.[38,42] It is important to consider that these self-reported measures are primarily driven by improvements in pain and may not complete describe a patient's recovery from TKA.[38] When physical impairments and performance-based outcomes are considered, the recovery trajectory is different.[33,38,42] Although patients report improvements in their ability to walk overground and climb stairs early after TKA, objective measures of these tasks indicate a loss of function in the first few weeks after surgery. Performance in these tasks gradually starts to improve in the subacute recovery period.[33,38,42] Even when patients are considered fully recovered 12 months after TKA, there is no clinically meaningful improvement in strength or performance-based measures of function beyond preoperative levels.[42] These residual impairments are even more dramatic when patients after TKA are compared to older adults without joint pathology.[54]

Although subjects are discharged from rehabilitation and are no longer routinely involved in orthopedic care, they continue to demonstrate functional deficits compared to age-matched samples. The residual impairments after TKA are concerning since they may increase the socio-economic burden of the disease. As previously highlighted, the demographic of the population of individuals requiring a TKA is shifting to a younger working age.[7,8] Therefore, an increasing number of subjects need to return to more demanding work activities after the surgery. Secondly, individuals undergoing TKA are more physically active compared to several decades ago[55] and they may seek TKA to return to sport participation. This class of individuals

may not fully benefit from rehabilitation protocols that target lower-level functional abilities such as walking, stair climbing, and rising from a chair.

A randomized controlled trial was designed to test whether the addition of neuromuscular electrical stimulation (NMES) to a progressive strengthening exercise rehabilitation protocol would produce better outcome following TKA surgery.[10] Subjects were randomized to a progressive strengthening protocol or a progressive strengthening protocol and NMES. This trial also had an embedded cohort of subjects who met all the inclusion criteria, but were unable to participate in the clinical trial due to geographic constraints or inability to attend the initial testing sessions. Subjects in the embedded cohort participated in unrestricted physical therapy in the community, although progressive strengthening or NMES were not the standard rehabilitation approach. The results of this randomized controlled trial showed that the addition of NMES to progressive strengthening did not produce better outcomes than progressive strengthening alone. However, subjects enrolled in either arm of the clinical trial (Progressive Strengthening or Progressive Strengthening plus NMES) had better performance in the timed up and go test (TUG), stair climbing time (SCT), and 6MW tests one-year following the surgery than subjects who participated in rehabilitation programs in the community. No comparison was made against a control group of older adults without knee pathology. Therefore, the second aim of this dissertation was to compare the functional performance of the clinical trial and standard of care groups assessed 12 months following TKA with the functional performance of a control group of older adults without knee pathology. We hypothesized that:

- Hypothesis 2.1. Participants enrolled in both progressive strengthening and standard of care rehabilitation protocol would have worse functional performance compared to older adults without knee pathology.

- Hypothesis 2.2. A greater proportion of participants enrolled in either progressive strengthening arm would have self-reported measure of function score, impairment based measures, and functional performance within a normal interval built using the data from the control group.

Methods

Participants

This study involved a secondary analysis of 239 participants who underwent unilateral TKA (figure 1). One-hundred ninety-nine of the participants in the TKA group were enrolled in a previously conducted randomized clinical trial. Participants for the clinical trial were recruited between July 2000 and November 2005. To be included in the clinical trial participants had to be between 50-85 years of age and be scheduled to undergo unilateral TKA. Participants were excluded if they had: 1) uncontrolled hypertension, 2) diabetes, 3) body mass index (BMI) above kg/m^2, 4) symptomatic OA in the contralateral knee (defined as self-reported knee pain greater than 4 on a 10-point analog scale), 5) other lower extremity orthopedic problems limiting function, or 6) neurologic impairment. The remaining 40 participants met all the inclusion criteria and were unable to participate in the clinical trial, but agreed to be tested 12 months after TKA. All participants underwent a tricompartmental, cemented TKA with a medial parapatellar surgical approach.

Additionally, 88 older adults were collected to be part of a control group (figure 1). To be included in the control group participants had to be between 50-85 years of age. Participants were excluded from the control group if they had: 1) pain in any of the joint in the lower extremity (defined as self-reported pain greater than 2 on a 10-point analog scale), 2) uncontrolled hypertension, 3) diabetes, 4) body mass index

(BMI) above kg/m^2, 5) lower extremity orthopedic problems limiting function, or 6) neurologic impairment.

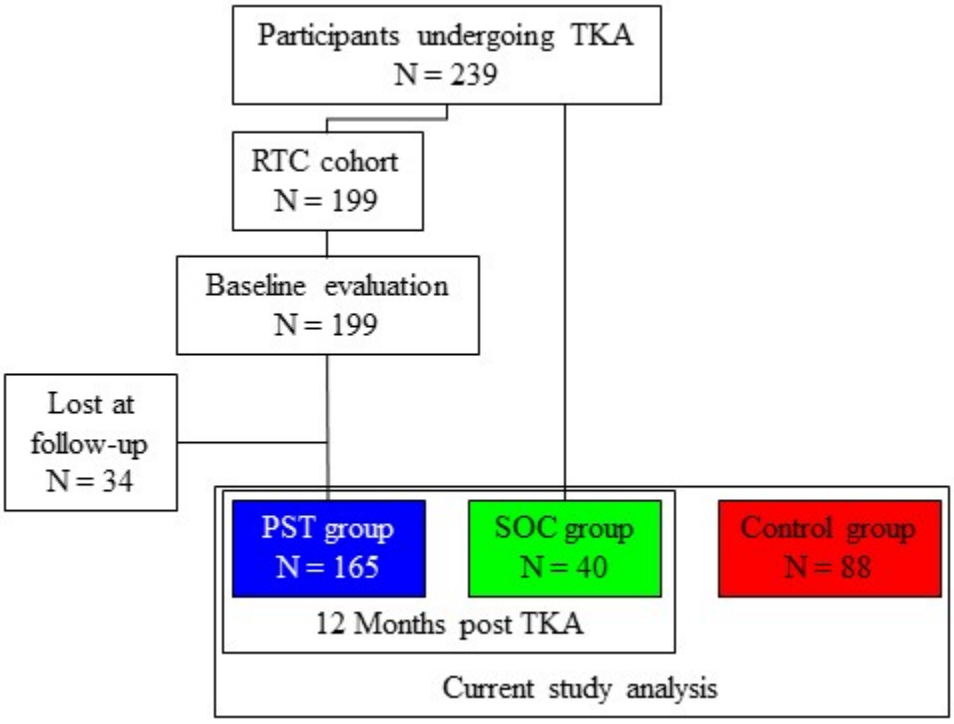

Figure 1 Flowchart of the participants included in the current study.

Rehabilitation after TKA

Following TKA, all participants received inpatient rehabilitation in the hospital. After discharge, the cohort enrolled in the clinical trial (199 participants) underwent home physical therapy followed by outpatient physical therapy. The outpatient treatment started three to four weeks after surgery and was conducted at the University of Delaware Physical Therapy Clinic. The RCT cohort was enrolled in at least 12 physical therapy visits over six weeks (two or three times per week). The

rehabilitation protocol was specifically designed to address physical impairments after TKA, including knee range of motion, patellar mobility, quadriceps strength, pain, and gait retraining.[10,56] Furthermore, the protocol included progressive strengthening (PST) exercises that targeted muscle groups in the lower extremity. Strengthening exercises were progressed by increasing the resistance to maintain 3 sets of 10 repetition intensity target.

The group of participants who underwent TKA but did not participate in the RTC (40 participants) were enrolled in outpatient physical therapy in the community, in which progressive strengthening was not the standard approach (standard of care [SOC] group).

Procedures

All participants underwent a functional evaluation. The participants included in the PST group were tested longitudinally at different time points after surgery. For the purpose of this study only the data obtained 12-months after surgery will be used for the analysis. Participants in both the SOC and control groups were tested only one time. This evaluation was 12-months after surgery for the standard of care group.

During the evaluation participants completed the Knee Outcome Survey – Activity of Daily Living (KOS-ADL), which is a valid questionnaire to measure self-reported knee function and has been extensively used in patients after TKA.[57,58] This questionnaire includes six questions that ask patients to rate the effect of six common knee symptoms on daily activity. Patients are asked to rate their symptoms from, “I do not have the symptom”, to, “The symptom prevents me from all daily activity”. The questionnaire also includes seven questions where patients are asked to rate their functional limitation during several different daily activities. Possible answers range

from, “Activity is not difficult”, to, “I am unable to do the activity”. Score are assigned to each answer on a six point scale from five (maximum score) to zero (minimum score). Total score is presented as percentage with 100% representing full knee function.

Active knee range of motion was measured with a standard goniometer. Knee extension range of motion was measured with the subjects laying supine with the feet resting on a four inches block to allow for hyperextension. Measurements were taken while the participants extended the knee “as hard as they could”.[59] Knee flexion range of motion was measured with the participants laying supine. Subjects were instructed to bring their heel towards their buttocks, “as far as possible”.[59]

Quadriceps strength was defined as the maximal voluntary isometric contraction on an electromechanical dynamometer (Kincom, Chattex Inc., Chattanoga, TN, USA). Participants were positioned according to the manufacturer recommendations and were secured to the dynamometer using waist and chest straps. The axis of rotation of the dynamometer was adjusted to match the axis of rotation of the knee and participants were then placed at 75° of knee flexion for testing. Participants first performed two sub-maximal and one maximal knee extensor isometric contraction to warm-up and to become familiar with the protocol. After one minute of rest, participants performed three maximal extension contractions with one minute rest between contractions. Strength was measured in Newtons (N) and was normalized to body mass (kg). The maximum of three trials was then used for further analysis.

Participants also performed three performance-based tests: the timed up and go (TUG), the stair climbing time (SCT), and the six-minute walk tests (6MW). For the

TUG, participants stood up from a chair without using the armrests, walked as fast as possible for a distance of 3m, turned around, and returned back to sit in the original chair. Time started on the investigator's command and stopped when the participants were fully seated in the chair.[60] For the SCT, participants ascended and descended a set of 12 steps (15cm rise, 20cm run), "as fast as possible while still being safe". If needed, participants were allowed to use one hand-rail, but participants were not allowed to skip steps. The use of handrail and the pattern of stair ascent and descent (step over step or step-to patterns) were recorded. Time started on the investigator's command and stopped when the participants touched the ground with both feet after the last step.[61,62] For the 6MW, participants were asked to walk as far as they could for 6 minutes along a 115 m square hallway. Participants were informed when they reached the second, fourth and fifth minutes. Running was not permitted. Participants were allowed to rest, if needed, but time was not stopped during rest.[61] These tests are recommended to measure performance in older adults with osteoarthritis or after joint replacement.[49]

Statistical analysis

Participants' characteristics

Due to the nature of a longitudinal study, 34 participants enrolled in the clinical trial did not undergo the functional evaluation at 12 months. The data from the functional evaluation executed at baseline (one month after TKA) were used to assess differences between the participants who underwent and the ones who did not undergo the functional evaluation at 12 months. These subgroups were compared using an independent sample t-test.

Sex distribution between the PST, SOC, and control groups were compared using a Chi-square test. Demographic characteristics (age, height, weight, and BMI) of the PST, SOC, and control groups were compared using a one-way analysis of variance (ANOVA) model for each variable.

Between group analysis – 12-Months

KOS-ADL score, knee range of motion, quadriceps strength, and performance-based tests were compared between groups (PST, SOC, control) using a One-way ANOVA model for each variable. When significant effects of group were found, Tukey-HSD post-hoc tests was performed to determine which groups were different.

Distribution analysis – 12-Months

Averages, standard deviations, and 95% confidence intervals were calculated for each variable in the control group. The proportion of subjects in both PST and SOC groups who achieved the lower bound of the confidence interval for KOS-ADL, MVIC, flexion ROM, and 6MW test and the upper bound of the confidence interval for TUG, SCT, and extension ROM was recorded. This number represents the frequency in which individuals in both groups achieved values within the confidence interval of the control group. The Chi-Square test was used to determine if there were significant differences in the proportions of subjects who achieved normal limits between groups (PST and SOC).

Quartile intervals for TUG, SCT, 6MW and quadriceps MVIC were built using the data of the control group and were used to categorize the performance in each test of participants 12 months following TKA. Four categories of performance were defined as follows: 1) exceptional performance (participants that performed above the

100th percentile of the control group), 2) high normal (participants that performed between the 51st and 100th percentile of the control group), 3) low normal (participants that performance between the 1st and 50th percentile of the control group), and 4) poor performance (participants that performed below the 1st percentile of the control group). Compared to the aforementioned analysis, this approach provided more information on the distribution of the performance score of participants after TKA because outcomes were not dichotomized. The proportion of subjects in each category was compared between the PST and SOC group using a Chi-square test.

Results

Participants' characteristics

At baseline, there were no differences in age, weight, height, BMI, KOS, knee flexion and extension ROM, and quadriceps MVIC for subjects in the PST group that attended the functional evaluation 12 months after TKA and the subjects in the PST group who did not (table 4). However, participants who attended the 12 month functional evaluation had better performance on the TUG, SCT, and 6MW tests compared to participants who did not attend the 12-month functional evaluation.

Table 4 Demographic and functional evaluation variables for the participants who did and did not attend the 12-months functional evaluation

	Attended 12-months N = 165		Did not attend 12-months N = 34		
	Avg	STD	Avg	STD	P-Value
Sex, % female	56		41		
Age, years	64.82	8.61	66.26	7.56	0.416
Weight, Kg	88.54	17.09	92.82	20.19	0.242
Height, m	1.71	0.10	1.73	0.09	0.488

BMI, kg/m2	30.16	4.97	30.93	4.91	0.456
KOS, %	0.69	0.13	0.69	0.17	0.936
Flexion ROM, °	110.73	12.15	112.46	12.20	0.487
Extension ROM, °	3.62	3.70	2.73	3.44	0.224
TUG, s	9.04	2.01	10.41	3.68	0.005*
SCT, s	16.98	6.31	24.81	23.95	0.000*
6MW, m	493.36	102.92	431.61	137.49	0.009*
Quadriceps MVIC, N\Kg	4.92	2.04	4.27	1.87	0.120
Abbreviation: Avg, Average; STD, standard deviation; BMI, body mass index; KOS, Knee Outcome Survey; ROM, range of motion; TUG, timed up and go; SCT, stair climbing time; 6MW, six minute walk; MVIC, maximal voluntary isometric contraction.					
*, Indicates significant differences between groups.					

The sex distribution was not similar between groups (p = 0.019, table 5), with the SOC group having a higher proportion of female participants. There were no differences between the PST, SOC, and control group for age and height (table 5). However, both the PST and SOC groups had greater weight and BMI compared to the control group (table 5).

Table 5 Demographic characteristics of the PST, SOC, and control groups.

	PST N = 165		SOC N = 40		Control N = 88			
	Avg	STD	Avg	STD	Avg	STD	F-Value	P-Value
Sex, % Female	44		65		56			0.019*
Age, years	64.90	8.58	66.45	8.95	64.46	8.65	0.67	0.514
Height, m	1.71	0.10	1.68	0.11	1.69	0.10	2.22	0.110
Weight, Kg	90.65	17.53	92.18	19.78	76.51	15.88	21.55	< 0.001*
BMI, Kg/m2	30.88	0.11	32.84	6.45	26.54	4.21	29.53	< 0.002*
Abbreviation: PST, progressive strengthening; SOC, standard of care; Avg, average; STD, standard deviation; BMI, body mass index.								
*, indicates significant differences between groups.								

Between group analysis – 12 Months

Thirty-eight participants in the PST group did not complete the 6MW test because this was not a primary outcome in the initial RCT. There was a significant effect of group for KOS-ADL, knee flexion and extension ROM, quadriceps MVIC, and performance of the TUG, SCT, and 6MW tests (for all variables, $p < 0.001$, figure 2). The Tukey post-hoc analysis revealed that the control group had better scores than the PST and SOC groups for variables. Compared to the SOC group, the PST group had greater KOS-ADL score (mean difference [MD]: 6%, $p = 0.002$), knee extension ROM (MD: 2.24°, $p < 0.001$), took less time to complete the TUG (MD: 0.91s, $p = 0.006$) and the SCT (MD: 4.05s, $p < 0.001$) tests, and walked greater distance during the 6MW (MD: 54m, $p = 0.035$) test (figure 2).

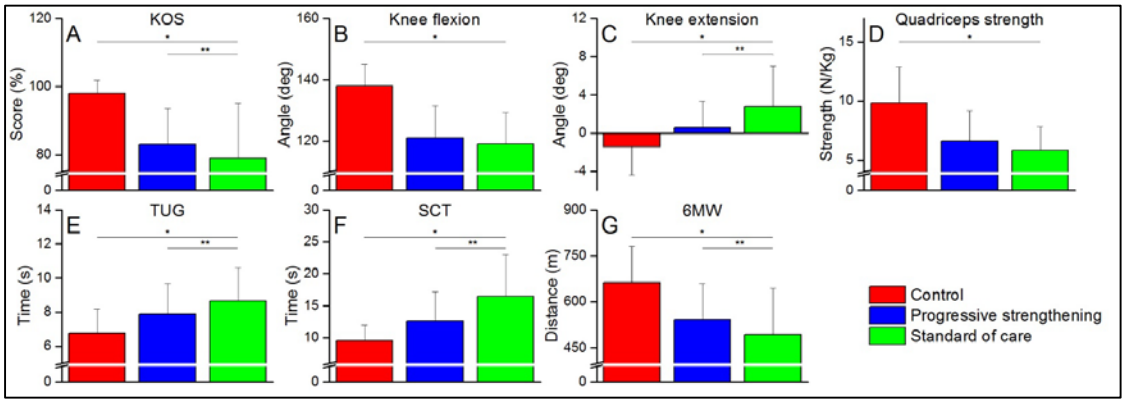

Figure 2 Average knee outcome score (A), knee flexion (B) and knee extension (C), range of motion, normalized quadriceps maximal voluntary contraction (D), time up and go (E) and stair climbing test (F) time, and distance walked in the six minute test (G) for the control (red bar), progressive strengthening (blue bar), and standard of care (green bar) groups. Error bars represent one standard deviation. *, indicates significant differences between groups (ANOVA); **, indicates significant differences between PST and SOC groups (Tukey post-hoc).

Distribution Analysis – 12 Months after TKA

The information used to calculate the lower bound value of the 95% confidence interval and the percentile ranking of the control group are reported in table 6.

Table 6 Average, standard deviation, and lower bound value of the 95% confidence interval for KOS-ADL score, knee flexion and extension ROM, quadriceps strength, and performance of the TUG, SCT, and 6MW tests. Percentile ranking for quadriceps strength, TUG, SCT, and 6MW tests.

			95% Confidence interval	Percentile		
	Avg	STD	Lower Bound	1st	50th	100th
KOS, %	98	4	97	NA		
Flexion ROM[a], °	139	8	137			
Extension ROM[a], °	-2	3	-1			
Quadriceps MVIC, N/Kg	9.38	2.81	8.79	2.19	9.81	16.48
TUG, s	6.63	1.41	6.92	10.97	6.45	4.24
SCT, s	9.71	2.48	10.23	17.83	9.25	5.87
6MW[b], m	652.90	109.40	629.78	432.20	636.56	1038.14
Abbreviation: Avg, average; STD, standard deviation; KOS, Knee Outcome Survey; ROM, range of motion; MVIC, maximal voluntary isometric contraction; TUG, timed up and go; SCT, stair climbing time; 6MW, six minute walk.						
[a], Range of motion measure were rounded to the nearest degree to match the goniometer scale.						
[b], The sample size of the PST group for the six minute walk calculation is equal to 127.						

A higher proportion of participants in the PST group achieved the lower bound cut-off for quadriceps strength (PST: 18%; SOC: 5%, p = 0.039) and SCT test (PST: 34%; SOC: 18%, p = 0.041, table 7) when compared to the SOC group. Although knee extension ROM and TUG test had similar proportional distribution to quadriceps

strength and SCT, this result was not significantly different between groups (extension ROM, PST: 30%; SOC: 15%, p = 0.060; TUG, PST: 35%; SOC: 20%, p = 0.079). Similar results were observed when the performance of the participants after TKA was categorized using the percentile distribution of the control group. Only one patient of the PST group achieved performance on the TUG greater than the 100th percentile of the control group. For all other measures, no participants exceeded the performance of the control group. In both groups the majority of the participants were categorized as low performance (between 1st and 50th percentile of the control group). For all measures, more participants in the PST group were categorized as high normal (MD: from 7 to 10%). In contrast, more participants in the SOC group were categorized as poor performance (MD: from 2% to 24%, table 7)

Table 7 Percentage of patients who achieved the lower bound cut-off of the 95% confidence interval of the control group. Percentage of participants included in each performance category. The categories were defined using the data from the control group.

		Lower bound Analysis		Percentile ranking Analysis				
		Proportion	p-value	exceptional	high normal	low normal	poor	p-value
KOS	PST	16	0.314	NA				
	SOC	10						
Flexion ROM	PST	4	0.718					
	SOC	3						
Extension ROM	PST	30	0.060					
	SOC	15						
TUG	PST	35	0.076	0.61	21	73	5	0.277
	SOC	20		0	13	75	13	

SCT	PST	34	0.041[a]	0	24	65	11	0.001[a]
	SOC	18		0	15	50	35	
6MW	PST	23	0.288	0	21	65	14	0.071
	SOC	15		0	14	52	33	
MVIC	PST	18	0.039[a]	0	10	88	1	0.092
	SOC	2		0	0	98	3	

Abbreviation: TUG, timed up and go; SCT, stair climbing time; 6MW, six minute walk, MVIC, maximal voluntary isometric contraction, PST, progressive strengthening, SOC, standard of care;
[a], Proportion significantly different between groups.

Discussion

This study compared the performance of three groups: 1) participants 12-months after TKA who underwent a PST rehabilitation protocol; 2) participants 12-months after TKA who underwent SOC rehabilitation; and 3) older adults without knee pathology. The results of this study support our first hypothesis, as both participants groups had worse self-reported scores, greater physical impairments and lower performance-based outcomes compared to the control group. The second hypothesis was partially supported by the data; a higher proportion of participants enrolled in PST rehabilitation achieved the lower bound cut-off for quadriceps strength and SCT tests. There was a trend toward higher proportion in the PST group for achieving the lower bound cut-off for TUG and knee extension ROM, but no differences were observed for KOS-ADL, knee flexion ROM and 6MW test. Similar trends were also observed in the percentile rank distribution: a higher proportion of participants in the PST performed in the high normal and low normal categories when compared to the SOC group.

The results of this work are in line with what has been previously reported. On average, participants after TKA have lower perception of functional abilities,[63–65] less range of motion at the knee,[54,64] impaired quadriceps strength,[54,64,65] and worse

performance on performance-based tests,[54,64] compared to older individuals without knee pathology. Furthermore, the majority of participants after TKA did not achieve the lower-bound value of the 95% confidence interval and performed in the low normal and poor performance categories. This is concerning considering that both groups underwent outpatient physical therapy interventions.[10] Current rehabilitation protocols may not fully restore knee function, strength, and performance after TKA. Failure to restore knee function by 12 months after TKA may be deleterious, as previous studies have shown that these measures plateau around 12 months following TKA,[34,61,66] and no meaningful gains have been observed with longer term followups.[66]

Compared to the SOC group, participants enrolled in the PST rehabilitation program had greater knee extension range of motion and performance on the TUG, SCT, and 6MW tests. The greater strength and performance measured in participants who underwent PST rehabilitation may also have influenced their perception of functional abilities. Compared to the SOC group, the PST group had higher KOS-ADL score at 1 year. This is in line with recent evidence showing that the type of post-TKA rehabilitation may influence outcomes: protocols that include strengthening and intensive functional exercises appeared to produce better outcomes than standard rehabilitation protocols.[10,26,67]

Understanding whether different rehabilitation protocols restore normal physical function is imperative, especially considering the shift in demographic of patient undergoing TKA.[8] Moffet et al.[26] randomized 77 patients two months after TKA to receive either intensive functional rehabilitation or standard rehabilitation. The authors reported that patients who underwent intensive functional rehabilitation

had greater performance on the 6MW test compared to patients who underwent standard rehabilitation. Furthermore, 53% of the patients in the intensive functional rehabilitation group had performance on the 6MW test within the normal limits of a group of healthy individuals. In the current study, the proportion of participants achieving the lower bound of the control group performance during the 6MW test was similar between the PST (23%) and SOC group (15%). The high number of missing data points for 6MW test in the PST group may explain in part this lack of statistically significant between group differences for this performance measure. The other possible explanation is that neither the PST nor the SOC protocol fully targeted factors that could influence 6MW performance. The intensive rehabilitation protocol developed by Moffet et al.[26] included endurance exercises that likely increased participants' aerobic capacity and endurance. Targeting these factors will likely generate an improvement of a longer duration test such as the 6MW.

A higher proportion of participants that underwent PST rehabilitation achieved the lower bound cut-off of the 95% confidence interval for quadriceps strength compared to participants enrolled in SOC rehabilitation. Aggressive and progressive strengthening exercises, hallmark of the PST rehabilitation protocol, may therefore be more effective in restoring normal knee strength after TKA. Higher quadriceps strength may also have an impact on the functional performance of participants in the PST group. Several studies have shown that quadriceps strength is the strongest predictor of performance in patients following TKA.[10,33,68,69] Stair climbing is a challenging functional activity for patients after TKA,[68,70] as it generates large external flexor moment at the knee, which is primarily counteracted by the action of the quadriceps muscle.[70,71] Therefore, it is not surprising that a higher proportion of

participants in the PST group achieved the normality cut-off for SCT test compared to the participants in the SOC group. Additionally, a higher proportion of participant in the PST group were characterized in the high normal and low normal categories of performance for SCT test. Similar trends were also observed for TUG test performance, which is also influenced by quadriceps strength.[33] Taken together, these results may suggest that PST rehabilitation may be more effective in restoring normal physical function 12 months following TKA compared to SOC rehabilitation.

Even after attending a rehabilitation program specifically designed to target strength deficits, participants in the PST group had 35% lower quadriceps strength compared to the control group. Quadriceps weakness is one of the primary factors limiting functional performance after TKA.[33] Longitudinal studies have shown that quadriceps strength returns to pre-operative levels by 6-months after TKA,[33,42] but improvements beyond pre-operative levels are rare and patients after TKA exhibit asymmetrical quadriceps strength when compared to control groups.[66] Further research is needed to assess why individuals after TKA have residual strength deficits, even after joint pain and effusion have been resolved, and patients attend a course of outpatient rehabilitation. For example, the use of neuromuscular electrical stimulation (NMES) may promote strength gains in patients following TKA.[72] Although application of NMES did not produce better outcome during in the late phase of recovery (at least 2 months after TKA),[10] the use of NEMS in the early pre-operative phase successfully attenuated the important early decrease of quadriceps strength related to arthrogenic inhibition.[12,72] However, pre-operative status may limit the ability of patients to re-gain strength after TKA, as patients usually undergo surgery

with significant strength and performance deficits generated by living several years with OA symptoms.

Limitation

The pre-operative performance on the TUG, SCT, and 6MW for the participants in PST group who participated in the 12 month follow up appointment was higher compared to the group who did not return at follow up. While this is considered a limitation, it also represent a characteristic of longitudinal trials. Patients with lower performance at baseline tend to have a higher number of co-morbidities that may prevent participation in subsequent follow up visits. It is likely that a similar pattern would have been observed in the SOC group if followed longitudinally. The cross-sectional design limits the ability to understand whether the difference measured 12-months following TKA were present before surgery. There was a higher proportion of female participants in the SOC and control groups compared to the PST group. However, stratifying the normality cut-off values by gender and/or age groups was not possible due to the limited number of participants included in the SOC group. The 6MW test was not a primary measure of the randomized trial and was the last measure collected, which is likely related to the high number of missing data (33%) for this test in the PST group.

Conclusion

Despite the limitations, we found that participants enrolled in a rehabilitation protocol that includes PST exercises are more likely to achieve normal values in terms of knee strength and performance based test 12 months after TKA. PST rehabilitation

protocols may be more effective in restoring normal physical function 12 months following TKA compared to SOC protocols.

Chapter 3

FUNCTIONAL AND BIOMECHANICAL RECOVERY AFTER TOTAL HIP ARTHROPLASTY

Introduction

Total hip arthroplasty (THA) is the standard treatment for end-stage hip osteoarthritis.[1] This surgical procedure has been defined as the "surgery of the century" for its excellent outcomes and cost-effectiveness.[73] Patients are extremely satisfied of the outcomes of this procedure,[53] therefore it is not surprising that the worldwide rate of utilization of THA has been steadily increasing over the past 10 years.[2] Currently, there are 332,000 THA procedure performed annually in the United States[51] and this number is projected to increase to 550,000 by 2030.[3]

Patient-reported outcomes and prosthesis survival have been extensively used to evaluate the recovery and surgical success after THA.[74–76] Patients commonly report reduction of hip joint pain and improved perception of functional abilities soon after surgery.[75–77] These improvements are maintained several years after THA.[76] However, when patients' improvements are evaluated on the individual basis, approximately 14 to 36% of patients did not improve or reported worse scores on the WOMAC questionnaire 12-months following THA.[74] Considering that improvements in patient-reported outcomes may be driven by the reduction of pain,[33,38,78] the sole use of these outcomes measures to evaluate recovery may overestimate the real functional gains of patients following THA.[79]

Recent longitudinal analysis have shown that there is substantial improvement in self-reported measures of function in the first 3-months following the surgery.[80] In contrast, improvements in performance-based measures and hip range of motion were observed later, between 3- and 12-months after THA.[80] Although performance improves during the later phases of recovery, performance-based tests, such as stair climbing time, five time sit to stand, timed up and go, and six-minute walk, continue to be worse in patients 12-months following THA when compared to older adults without knee pathology.[77] Similarly, strength deficits of the knee and hip, are found one month after THA [77] and do not fully resolve even 1 year after THA when compared to control group.[77]

Impairments in strength and range of motion may drive the biomechanical abnormalities measured in patients after THA. During gait, patients after THA exhibit reduced hip range of motion, lower hip flexion angle at initial contact, less hip extension at terminal stance and altered hip joint moments compared to control participants without hip pathology.[81–84] These gait adaptations may arise in the presence of hip osteoarthritis symptoms, such as pain and strength deficits,[85] and may not return to normal after THA.[83] Furthermore, patients with end stage hip osteoarthritis exhibit increased trunk lean and pelvis drop when completing the stance phase of gait with their surgical side.[78,86] Although a cross-sectional study reported no between side differences in trunk and sacrum oscillation amplitude in patients at least 3 weeks after THA,[87] no longitudinal study have analyzed the effect of THA surgery on the recovery of trunk and pelvis biomechanics.

Therefore, the purpose of this chapter was to identify predictors of functional and biomechanical recovery of patient undergoing THA surgery. Specifically, we hypothesized:

- Hypothesis 3.1. Before surgery, patients will present with lower hip extension angles and external hip extension moments in terminal stance on the side scheduled for surgery, but these asymmetries will be resolved by 3 months post THA.

- Hypothesis 3.2. Before surgery, patients will walk with greater trunk lateral lean during the stance phase of gait on the side scheduled for surgery, and these asymmetries will be resolved by 12 months following THA.

- Hypothesis 3.3. Hip abductor and quadriceps strength at three months will be greater than pre-operative, while strength at twelve months will be greater compared to 3 month.

- Hypothesis 3.4. Clinical impairments at three months will predict functional status twelve months after THA.

- Hypothesis 3.5. Improved abductor and quadriceps strength from three and twelve months will predict better functional performance twelve months following the surgery.

Methods

Participants

Participants between 40 and 85 years of age were included in this study. To be included in the patients group, participants had to be scheduled to undergo THA between March 2012 and September 2014 received a letter from their surgeon informing them about the study. Interested participants were screened for eligibility through a phone interview. Participants were excluded if they had: (1) neurological, vascular or other lower extremity musculoskeletal conditions that affected gait or functional performance; (2) self-reported lack of sensation in the foot or lower

extremity; (3) uncontrolled hypertension; (4) history of cancer in the lower extremity; (5) were unable to walk short distances (10m) without an assistive device; (6) were moving within the next year (only THA group); and (7) had pain in either hip or knee (control group).

Data from a control group of healthy older adults were also used in this study. Participants in the control group were between 40 and 85 years of age and did not have any lower extremity pathology. All participants signed an informed consent form that was approved by the Human Subjects Review Board prior to participation in any portion of the study.

Procedure

Participants in the THA group underwent a functional and biomechanical evaluation at three different time points: before surgery, and 3- and 12-months following the surgery. Participants in the control group underwent only one functional evaluation at one time point.

Functional evaluation

Patients completed the Hip Harris Score (HHS), which is a valid and reliable scale that have been used extensively to evaluate outcomes of patients following THA surgery.[88] This questionnaire asks patients to self-rate their symptoms and dysfunction related to their hip pathology. Furthermore, it includes some impairment measures, such as presence of contracture and hip range of motion, which are assessed by the clinician or researcher who administered the scale. The total possible score is 100, which represents the absence of limitations.

Participants completed the Hip Outcome Survey,[89] which is a questionnaire that includes six questions that ask patients to rate the effect of six common knee symptoms on daily activity. Patients are asked to rate their symptoms from “I do not have the symptom” to “The symptom prevents me from all daily activity”. In addition, the questionnaire includes 7 questions where patients are asked to rate their difficulty performing several different daily activities. Possible answers range from “Activity is not difficult” to “I am unable to do the activity”. Scores are assigned to each answer on a 6 point scale from 5 (maximum score) to 0 (minimum score). Total score is presented as a percentage with 100% representing full hip function.

Active-assisted range of motion (ROM) was measured for hip flexion, abduction, adduction, internal rotation, and external rotation as part of the HHS using a goniometer.[59] Subjects were asked to move their limb into end range and the investigator provided support and a slight overpressure. Hip flexion was measured supine with the knee flexed. Hip abduction and adduction were measured supine with the knee extended. Hip internal and external rotation were measured in a seated position. The total hip ROM was quantified as the sum of all individual range of motions measured in the HHS.

Hip abductor muscle strength was measured during an isometric hip abduction contraction using a hand-held dynamometer (Lafayette Manual Muscle Testing System; Model 01165; Instrument Company, Lafayette, IN).[90] Subjects were positioned in sidelying and a non-elastic strap was positioned around the subjects’ distal thigh to provide resistance. The hand-held dynamometer was positioned proximal to the lateral femoral condyles and its position was held constant between trials to avoid changes in the resistance moment arm. Subjects were asked to push into

the strap (abduct their hip) as hard as possible. The maximal trial from three attempts was used as the maximal isometric contraction. This method has also been shown to be valid and reliable in older adults.[90] Strength values are reported as % of body mass (Kg).

Maximal voluntary isometric strength for the quadriceps muscle was measured using an electromechanical dynamometer (Kin-Com, Chattex Inc., Chattanoga, TN, USA).[33,91] Participants were secured to the dynamometer with the knee positioned at 75° of flexion. Two submaximal contractions (50% and 75%) and one maximal contraction (100%) were completed to familiarize participants with the protocol and to warm-up. After one minute rest, three maximal contractions were performed with one minute of rest between contractions to avoid fatigue. Pain was assessed during isometric strength testing using a 0 to 10 scale where 0 represented no pain and 10 was the worse pain imaginable. Force data were recorded in Newtons using a force transducer located at the distal anterior tibia two centimeters proximal to the lateral malleolus. Data were collected at 200 Hz using custom Labview software (National Instrument, Austin, TX, USA) and normalized according to body mass (Kg).

Participants also performed three performance-based tests: the timed up and go (TUG), the stair climbing time (SCT), and the six-minute walk tests (6MW). For the TUG, participants stood up from a chair without using the armrests, walked as fast as possible for a distance of 3m, turned around, and returned back to sit in the original chair. Time started on the investigator's command and stopped when the participants were fully seated in the chair.[60] For the SCT, participants ascended and descended a set of 12 steps (15cm rise, 20cm run) "as fast and as safe as possible". If needed, participants were allowed to use one hand-rail, but participants were not allowed to

skip steps. The use of handrail and the pattern of stair ascent and descent (step over step or step-to patterns) were recorded. Time started on the investigator's command and stopped when the participants touched the ground with both feet after the last step.[61,62] For the 6MW, participants were asked to walk as far as they could for 6 minutes along a 115 m square hallway. Participants were informed when they reached the second, fourth and fifth minutes. Running was not permitted. Participants were allowed to rest, if needed, but time was not stopped during rest.[61] These tests are recommended to measure performance in older adults with osteoarthritis or after joint replacement.[49]

Biomechanical Testing

Eight infrared cameras (Vicon Motion Systems Ltd, Oxford, UK) were used to detect the position of retro reflective markers at 120Hz through a collection volume that was approximately 1.2m wide, 1.5m long, and 2.3m high. Sixteen-millimeter spherical retro-reflective markers were placed bilaterally on the acromion process, iliac crest (aligned vertically with the greater trochanter), greater trochanter, lateral and medial femoral condyle, lateral, and medial malleolus, head of the 1st and 5th metatarsal bone, and two markers on the heel. Rigid thermoplastic shells with four markers were secured bilaterally on the shank, thighs, and upper-back and were used to track the motion of these segments during the dynamic walking trials. Pelvic motion was tracked using a rigid thermoplastic shell with three markers placed below the line between the two posterior superior iliac spines. A standing calibration trial was taken to identify knee and ankle joint centers and create the segment coordinate systems. Functional hip joint centers were determined using a built-in algorithm that calculates the most likely intersection of all axes (effective joint center) and most likely

orientation of the axes (effective joint axis) between the pelvis and femur based on a separate dynamic calibration trial in which subjects performed hip flexion, extension, abduction, and circumduction during single leg stance.[92] Joint angles for the ankle, knee, hip, and trunk joints were calculated using Euler X-Y-Z sequence corresponding to sagittal, frontal, and transverse rotations sequence. Two force platforms (Bertec Corporation, Columbus, OH) were embedded into the floor and recorded synchronous ground reaction forces at 1080 Hz. Subjects walked along a 10m walkway at their normal self-selected speed. Subjects were shod in their own shoe- wear, but subjects were instructed not to wear sandals for the testing. Self-selected speed was measured during three practice trials prior to data acquisition. Subjects completed five successful trials for each leg. A successful trial was defined as a walking trial that was within 5% of the initial self-selected speed in which at least one foot landed completely within the force plate area and there was no apparent targeting towards the force plate by the subject.

Data Analysis

Visual3D software (C-Motion Inc., Germantown, MD) was used for kinematic and inverse dynamic analyses. Kinematic and kinetic data were filtered at 6Hz and 40 Hz, respectively using a second-order phase corrected Butterworth filter. Gait speed was measured using the “temporal distance” pipeline command of Visual3D. For each limb hip sagittal and frontal angle were calculated during the stance phase of gait normalized to 100%. Sagittal and frontal hip moments were calculated in the same phase of gait, normalized to body mass (kg) and height (m), and reported as internal moments. Frontal plane trunk movement was measured in two ways. First, peak trunk angle was defined as the maximum trunk angle towards the stance side during the

stance phase of gait. This angle was the resultant angle between the trunk segment and the pelvis segment. Second, frontal plane trunk position in the lab coordinate system was measured to remove the effect of altered pelvis position on the trunk angle calculation. This was calculated as the trunk angle in the plane perpendicular to the walking direction and represents what is clinically referred to as trunk lean. Due to the nature of observational gait analysis, clinical observation of trunk lean may not delineate pelvic contribution. Trunk angle in the frontal plane, independent of pelvis position, was defined as lateral trunk lean for the purpose of this paper. Similar to peak trunk angle, peak lateral trunk lean in the lab coordinate system was calculated as the maximum trunk lean angle towards the stance side. Positive values indicate lateral trunk lean toward the stance side for both trunk angle and lateral trunk lean.

Pelvic drop was also evaluated by measuring the rotation of the pelvis in the lab coordinate system. This angle was calculated as the angle of the pelvis segment about an axis parallel to the direction of walking. This conveys information of the frontal plane pelvis rotation, irrespective of the position of the femur segment. This was defined in this paper as pelvis rotation. Negative values indicate rotation in which the contralateral iliac crest is depressed relative to the hip (akin to hip adduction).

The following biomechanical variables were then used for the analysis: peak sagittal hip angle and moment during the weight acceptance and terminal stance phase of gait; peak frontal hip angle during weight acceptance; peak trunk lean angle and pelvis drop angle during weight acceptance. These variables were calculated for each limb.

Statistical Analysis

A 3 (time point) x 2 (limb) ANOVA model with repeated measure on both time point and limb was used to assess biomechanical and strength measures. If a significant interaction was found, a paired sample t-test was used to measure difference between limbs (biomechanical variables) or between time points (strength variables).

A 3-way repeated measure ANOVA was used to measure change in functional performance between the three time points. Separate hierarchical regression models were used to predict performance on functional tests (TUG, SCT, 6MW) at twelve months based on the functional status at three months following the surgery. Covariate predictors, including age, BMI, and sex were inserted in the first step of the model. Performance in the specific test at 3-months was entered in the second step. Pain level, total hip range of motion (taken from the HHS), and quadriceps and hip abductors strength at 3-months were entered separately in the third, fourth, fifth, and sixth steps of the model, respectively.

Separate hierarchical regression models were used to predict performance on functional tests (TUG, SCT, 6MW) at 12-months following the surgery based on the change of hip abductor and quadriceps strength between 3 and 12 months. Covariate predictors, including age, BMI, and sex at 3 months were inserted in the first step of the model. Performance on the specific test at 3-months was entered in the second step. Change in pain level between three and twelve months were entered in the third step. Change in total range of motion (taken from the HHS) was entered in the fourth step of the model. Change of operated side quadriceps strength and hip abductor strength between three and twelve months were entered separately in the fifth and sixth steps of the model.

The hip abductor and quadriceps strength, and performance on the TUG, SCT, and 6MW of the control group were descriptively compared with the data from the THA group at twelve-months following the surgery.

Results

Participants

Thirty-two patients after THA completed the functional and biomechanical evaluation at all three time points and were included in this analysis (figure 3). Twenty-five participants were included in the control group. Demographic information of the sample can be found in table 8.

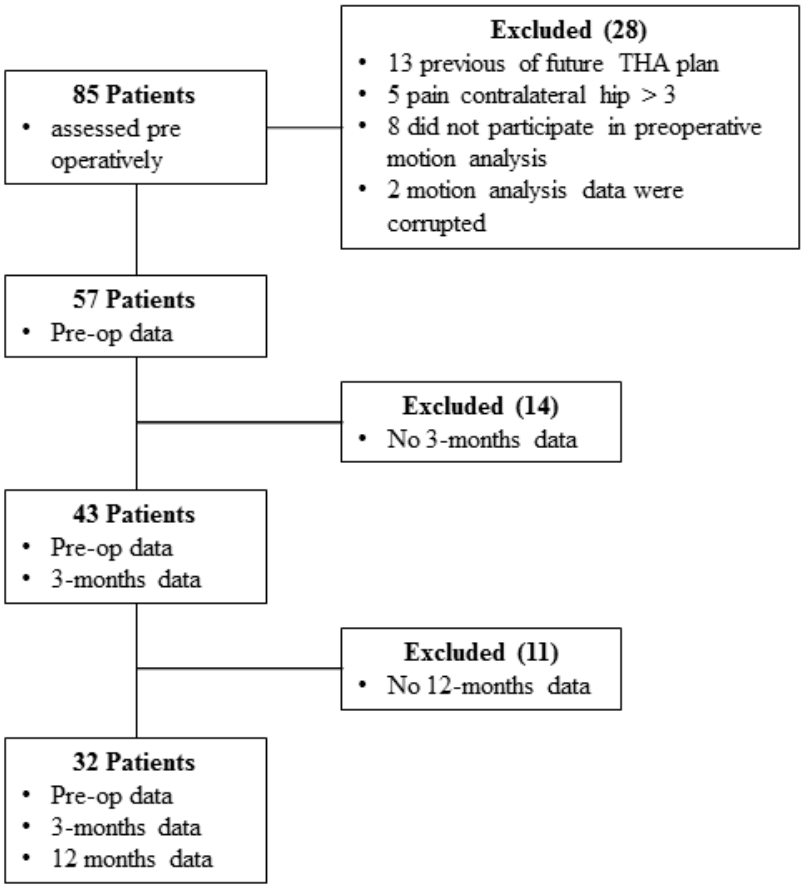

Figure 3 Flowchart of patients' enrollment and analysis at each time points.

Biomechanical variables

Significant time*limb interactions were found for peak hip flexion ($F = 13.152$, $p = 0.001$, figure 4) and extension angle ($F = 54.159$, $p < 0.001$); peak extension moment ($F = 13.137$, $p = 0.001$); and peak pelvis drop ($F = 12.171$, $p = 0.001$). For the biomechanical variables that did not demonstrate an interaction effect, there were significant main effects of time ($p < 0.005$). In addition, all variables except peak hip adduction angle and abduction moment ($F = 0.715$, $p = 0.404$ and $F = 2.267$, $p = 0.142$, respectively) had a main effect of limb

The post-hoc analysis revealed that peak hip flexion angle was significantly different between limbs before surgery ($p < 0.001$) but not three- and twelve-months following surgery ($p = 0.079$ and $p = 0.785$, respectively). Hip extension angle was significantly different between limbs before surgery and three-months after surgery ($p < 0.001$ and $p < 0.001$, respectively), but not twelve months following surgery ($p = 0.057$). Hip extension moment was significantly different between limbs before surgery ($p = 0.001$), but not after surgery ($p = 0.055$ and $p = 0.703$, respectively). Hip flexion moment was significantly different between limbs at each time point ($p = 0.001$, $p = 0.001$, and $p = 0.037$, respectively). Both trunk lean angle measures (pelvis and lab coordinate systems) were significantly different between limbs at all three time point ($p < 0.045$). Pelvis drop angle was significantly different between limbs before surgery, with greater contralateral pelvis drop during the stance phase on the surgical side ($p = 0.001$). After surgery, there were no significant differences between limbs ($p > .211$), which was mainly driven by an increase of drop angle in the non-surgical side.

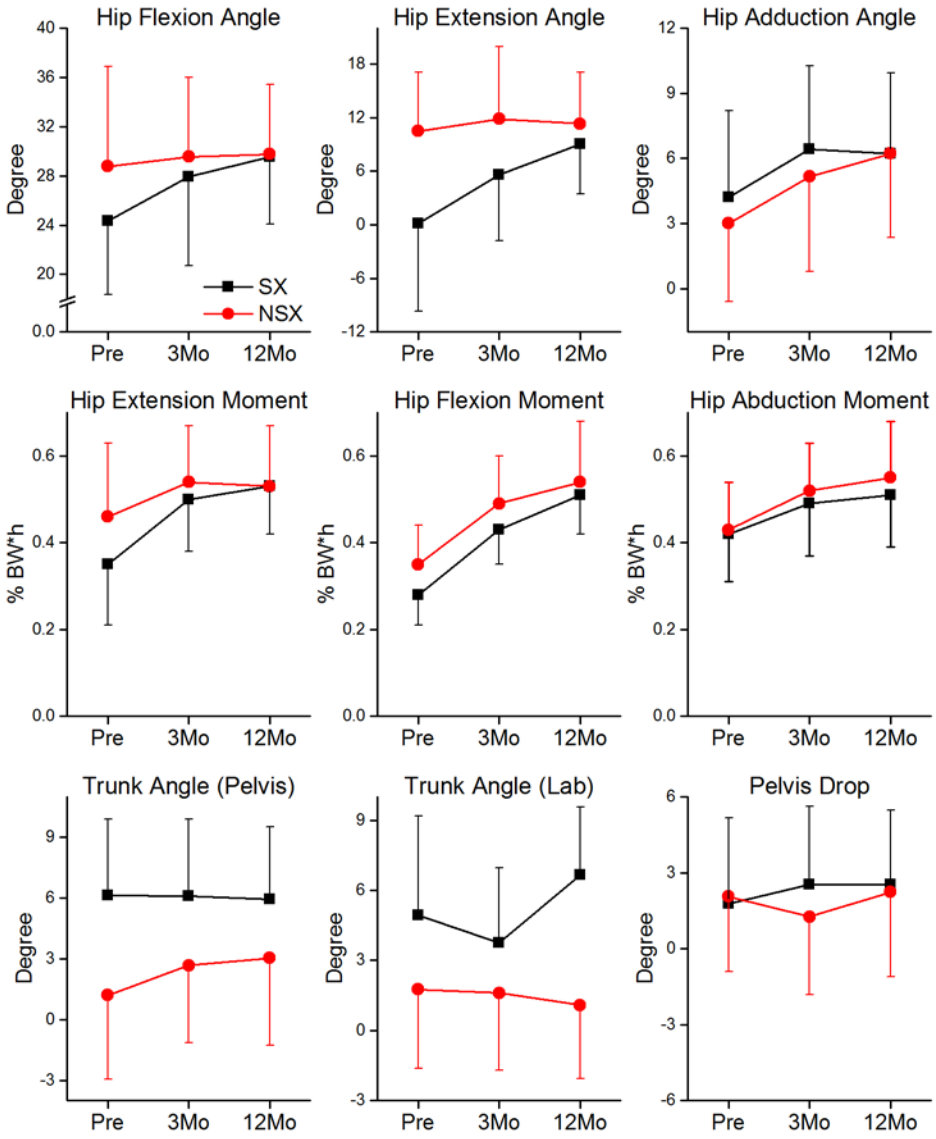

Figure 4 Biomechanical variables for the surgical (SX, black line) and non-surgical leg (NSX, red line) of the THA group at the three data collection time points.

Functional variables

Significant main effect of time was found for HHS ($F = 238.383$, $p < 0.001$, table 8), HOS ($F = 146.65$, $p < 0.001$), hip total range of motion ($F = 49.235$, $p <$

0.001), TUG (F = 38.788, p < 0.001), SCT (F = 26.608, p < 0.001), and 6MW tests (F = 56.536, p < 0.001). The post hoc-analysis revealed significant improvements in all measures between the pre-operative and 3-month follow-up (p < 0.001). Significant improvements between three and twelve month sessions were also found for the HHS (p = 0.009), HOS (p = 0.001), TUG (p = 0.006), SCT (p = 0.015), and 6MW (p = 0.017). Compared to the control group, the THA group had worse performance-based test scores twelve months after THA (table 8).

Table 8 Demographic characteristics, self-reported measure of function, and performance on the functional test for the THA and control groups.

	Pre-Op	**3-Months**	**12-months**			**Control**	**Percent difference**
	Avg (SD)	Avg (SD)	Avg (SD)	F-Value	P-Value	Avg (SD)	CTL - THA 12mo
Sex, m/f	16/16			NA		11/14	NA
Age, years	64 (8)	64 (8)	65 (8)			68 (8)	
Height, m	1.72 (0.09)	1.73 (0.09)	1.73 (0.09)	2.282	0.141	1.66 (0.09)	
Weight, Kg	89.07 (22.65)	86.87 (21.14)	86.03 (22.84)	1.68	0.204	71.6 (16.33)	
BMI, kg/m2	29.71 (6.73)	28.72 (5.42)	28.40 (5.75)	2.18	0.149	25.49 (4.09)	
HHS, %	56.53 (12.63)	88.21 (10.40)	92.59 (6.74)	283.38	< 0.001	NA	
HOS, %	60.01 (16.64)	88.30 (9.93)	93.30 (6.36)	142.65	< 0.001		
Total hip ROM, °	167 (32)	202.40 (24.89)	205.31 (20.06)	42.44	< 0.001		
Gait Speed, m/s	1.14 (0.18)	1.30 (0.15)	1.36 (0.13)	43.56	< 0.001		
TUG, s	9.20 (2.51)	7.63 (1.56)	7.08 (1.14)	38.79	< 0.001	6.17 (1.20)	13%

SCT, s	16.80 (6.87)	12.51 (3.57)	11.59 (3.17)	26.68	< 0.001	9.83 (2.12)	17%
6MW, m	451.79 (98.70)	540.70 (84.37)	565.33 (97.41)	56.54	< 0.001	640.95 (78.60)	12%
Abbreviations: Avg, average; SD, standard deviation; BMI, body mass index; HHS, Hip Harris Score; HOS, Hip Outcome Survey; ROM, range of motion; TUG, timed up and go; SCT, stair climbing time; 6MW, six minute walk.							

A significant time*limb interaction was found for quadriceps strength ($F = 10.849$, $p = 0.002$, figure 5). The post-hoc analysis revealed that quadriceps strength on the surgical side significantly improved from pre-operative to 3-months ($p = 0,006$) and also from 3-months to 12-months ($p = 0.003$). In contrast, quadriceps strength of the non-surgical side did not improve during the same time points ($p = 0.333$ and $p = 0.479$, respectively). Between limb difference of quadriceps strength were observed pre-operatively and at three-month follow-up (both $p < 0.001$), but not at twelve-month after surgery ($p = 0.099$). Only a significant main effect of limb was found for hip abductor strength ($F = 33.336$, $p < 0.001$). At each time point hip abductor strength on the surgical side was lower compared to the non-surgical side ($p < 0.001$).

Twelve-months following THA, hip abductor strength on the surgical side was approximately 47% lower compared to the control group, while quadriceps strength exceeded the average performance of the control group (figure 5).

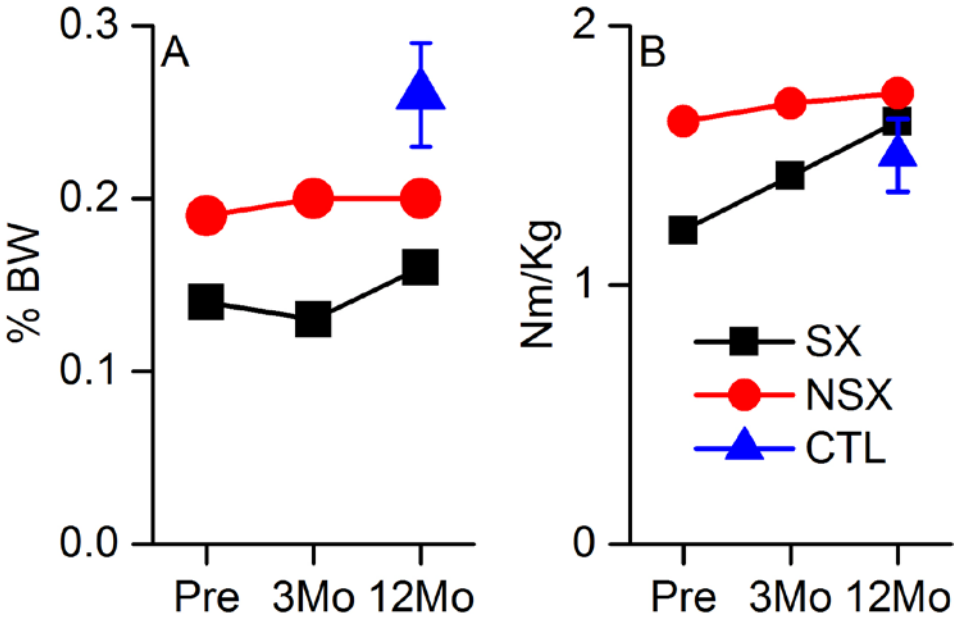

Figure 5 Hip abductor (A) and quadriceps (B) strength values for the surgical (SX, black line) and non-surgical (NSX, red line) leg of the TKA group, and the average between right and left leg of the control group (blue triangle). Error bars represent 95% confidence interval.

Predictors of performance

For each functional test, only the patients' performance on the specific functional test at three-months following the surgery significantly contributed to the variance of the performance twelve-months after surgery ($p < 0.001$, table 9) after accounting for the variance predicted by age, sex, and BMI.

Table 9 Regression analysis to predict performance at 12 months on the performance-based tests.

Timed up and go at 12 months					
	R^2	Adjusted R^2	Change Statistics		
			R^2 Change	F Change	p-value
Model 1: BMI_3mo, AGE,	0.229	0.147	0.229	2.778	0.06

SEX					
Model 2: 1 + TUG at 3mo	0.566	0.502	0.337	20.98	<0.001*
Model 3: 2 + Hip Pain at 3mo	0.574	0.493	0.008	0.491	0.49
Model 4: 3 + Hip ROM at 3mo	0.611	0.518	0.037	2.371	0.136
Model 5: 4 + Hip Abd Strength at 3mo	0.614	0.501	0.002	0.155	0.697
Model 6: 5 + Quad Strength at 3mo	0.622	0.49	0.008	0.489	0.492
Stair Climbing Time at 12 months					
	R^2	Adjusted R^2	Change Statistics		
			R^2 Change	F Change	p-value
Model 1: BMI_3mo, AGE, SEX	0.229	0.147	0.229	2.778	0.06
Model 2: 1 + TUG at 3mo	0.516	0.445	0.287	16.016	<0.001*
Model 3: 2 + Hip Pain at 3mo	0.526	0.435	0.01	0.55	0.465
Model 4: 3 + Hip ROM at 3mo	0.545	0.436	0.019	1.033	0.319
Model 5: 4 + Hip Abd Strength at 3mo	0.545	0.412	0	0	0.993
Model 6: 5 + Quad Strength at 3mo	0.547	0.39	0.002	0.108	0.745
Six Minute Walk at 12 months					
	R^2	Adjusted R^2	Change Statistics		
			R^2 Change	F Change	p-value
Model 1: BMI_3mo, AGE, SEX	0.229	0.147	0.229	2.778	0.06
Model 2: 1 + TUG at 3mo	0.435	0.351	0.205	9.815	0.004*
Model 3: 2 + Hip Pain at 3mo	0.437	0.329	0.002	0.103	0.751
Model 4: 3 + Hip ROM at 3mo	0.439	0.304	0.002	0.085	0.772
Model 5: 4 + Hip Abd Strength at 3mo	0.455	0.296	0.016	0.706	0.409
Model 6: 5 + Quad Strength at 3mo	0.478	0.297	0.023	1.022	0.323
*, Singificnatly predict performance at 12 months.					

For TUG and SCT tests, the change in range of motion between three and twelve months following surgery significantly improved the model when predicting change of performance during the same period ($p = 0.030$ and $p = 0.041$, respectively, table 10) after account for the variance explained by age, sex, BMI and change in pain. No significant predictors were identified for the 6MW test performance.

Table 10 Regression analysis to predict the change in performance between 3 and 12-months post-surgery.

Change of Time up and Go between 3 and 12 months post THA					
	R^2	Adjusted R^2	Change Statistics		
			R^2 Change	F Change	p-value
Model 1: BMI, AGE, SEX	0.097	-0.003	0.097	0.966	0.423
Model 2: 1 + Change in pain	0.123	-0.012	0.026	0.767	0.389
Model 3: 2 + Change in hip ROM	0.277	0.132	0.154	5.321	0.03*
Model 4: 3 + Change in hip abd strength	0.277	0.096	0	0.007	0.934
Model 5: 4 + Change in quad strength	0.277	0.058	0.001	0.016	0.9
Change of Stair Climbing Time between 3 and 12 months post THA					
	R^2	Adjusted R^2	Change Statistics		
			R^2 Change	F Change	p-value
Model 1: BMI, AGE, SEX	0.009	-0.102	0.009	0.078	0.972
Model 2: 1 + Change in pain	0.098	-0.041	0.089	2.568	0.121
Model 3: 2 + Change in hip ROM	0.239	0.087	0.141	4.638	0.041*
Model 4: 3 + Change in hip abd strength	0.247	0.059	0.008	0.271	0.608
Model 5: 4 + Change in quad strength	0.262	0.037	0.015	0.457	0.506
Change of Six Minute Walk between 3 and 12 months post THA					
	R^2	Adjusted R^2	Change Statistics		
			R^2	F	p-

			Change	Change	value
Model 1: BMI, AGE, SEX	0.15	0.055	0.15	1.587	0.215
Model 2: 1 + Change in pain	0.15	0.019	0	0	0.991
Model 3: 2 + Change in hip ROM	0.183	0.019	0.033	0.997	0.328
Model 4: 3 + Change in hip abd strength	0.203	0.004	0.02	0.612	0.442
Model 5: 4 + Change in quad strength	0.213	-0.026	0.011	0.309	0.584
*, Singificnatly predict change in performance between 3 and 12 months.					

Discussion

This study measured the biomechanical and functional recovery during the first year after THA surgery. The results do not support the first three hypotheses. While hip flexion angle and extensor moment appear to improve early after surgery, other impairments, such as knee extension angle, may take longer than three months to improve to a level similar to the contralateral leg. Other biomechanical asymmetries, such as internal hip flexor moment in terminal stance, trunk lean angle and pelvis drop may not resolve after surgery. While quadriceps strength on the surgical side appeared to improve to a level similar to the non-surgical side at the twelve month follow up, there are no improvement in hip abductor strength, and patients continue to exhibit asymmetrical hip strength. Functional performance three-months following the surgery was the only predictor of performance at twelve months post-THA.

During gait, patients with end-stage hip osteoarthritis had asymmetrical hip biomechanical patterns[85] that favor of the hip that was not scheduled for surgery. The results of this study show that, after undergoing THA surgery, hip flexion angle and extensor moment of the surgical leg improve, and patients reached symmetrical pattern twelve months following the surgery. In contrast, patients continue to exhibit abnormal biomechanical patterns especially in the late stance phase when the hip goes

through extension. Although the post-hoc comparison indicates that hip extension angle was not significantly different between limbs twelve months after THA, an interlimb difference greater than 2° still persisted. Similarly, hip flexor moment appear to increase over time, but significant differences between sides were still present 12 months following the surgery.

Aberrant trunk and pelvis kinematics have been measured in patients with hip osteoarthritis[86,93] and may be related to hip abductor wekness.[85] The results of this study showed symmetrical trunk kinematics was not restored after THA. Before surgery patients walked with greater lateral trunk lean during the stance phase on the surgical side, and this pattern was maintained following the surgery. Furthermore, the surgery seemed to disrupt the kinematic at the pelvis, as contralateral pelvis drop and hip adduction angle increased on the non-surgical side after surgery. The severe weakness before surgery and the lack of hip abductor strength gains after the surgery might drive these poor biomechanical outcomes. In contrast, Vogt et al.[87] reported in a cross sectional study that there were no differences in trunk oscillation between stride on the operated and non-operated leg in patients at least three-weeks after THA. The same authors found that trunk oscillation was not different between the THA group and older adults without hip pathology. However, participants in the study of Vogt et al.[87] were tested on a treadmill, which may reduce compensation in the frontal plane. Additionally, the cross sectional design of that study does not allow conclusions about changes over time, since trunk movements before the surgery was not assessed. These discrepancies in methodology may in part explain the different results between the studies.

Our results, along with previous reports in this population, suggest that patients after THA perform functional activities with biomechanical abnormalities that reduce the demand on the affected joints and rely on compensations on the contralateral side. If these asymmetries are not corrected during rehabilitation, deficits may persist in the long term.[94] These abnormal patterns may bode poorly for the health of the replaced joint, as well as the contralateral joint. Post-operative impairments, such as reduction of hip range of motion or persistent muscle weakness, may play a role in these altered biomechanical patterns. However, the presence of biomechanical abnormality before surgery and the lack of changes of some of these deficits after surgery may suggest that these impairments may be learned behavior that developed in the presence of osteoarthritic pain and are not corrected from the surgery itself. Patients are often not aware of these abnormalities, as suggested by the fact that none of the patients reported moderate or severe limping in the HHS score 12 months following THA. Therefore, addressing and correcting these learned behavior may require targeted interventions. For example, providing feedback during different weight bearing exercises promoted more bi-phasic knee moment during gait and greater vertical ground reaction force symmetry during sit to stand in patients after total knee arthroplasty.[95] These types of feedback trainings can be easily applied to a population following THA and have the potential to reduce biomechanical abnormality associated with the surgery.

Weakness of the lower leg muscle is a common complaint of patients awaiting THA surgery.[96] Before surgery, the hip abductors and quadriceps muscles were 35% and 30% weaker on the surgical side compared to the non-surgical side. Following the surgery, the pattern of strength recovery is different between muscle groups.

Quadriceps strength significantly improve over time and performance between legs is similar 12 months following the surgery, suggesting symmetrical strength between sides. Furthermore quadriceps strength on the surgical side reached a level of performance that exceeded the average of the control group. In contrast, hip abductor strength does not improve after surgery and hip abductors strength on the surgical side is approximately 47% lower compared to the control group. Judd et al.[77] used similar methodology to assess recovery of strength following THA. Interestingly, they found that while abductor strength improved after the surgery and reached a level similar to healthy control, quadriceps strength did not. Several factors can explain these discrepancies. While Judd et al. included only patients undergoing a posterior THA approach, the current study included both anterolateral and posterior approach (14 vs. 18, respectively). Anterolateral approach results in increased risk of damaging the gluteus medius and the superior gluteal nerve.[97] The release of the gluteus medius insertion[98] may severely impact strength recovery after surgery by limiting aggressive strengthening interventions especially during outpatient physical therapy. Patients may have also attended different outpatient rehabilitation protocols due to the lack of standardized rehabilitation recommendation after THA.[99,100] The control group of the current study is almost 10 years older compared to the control group of the study of Judd et al.[77] This is an important age difference as quadriceps strength of older adults declined approximately 14% over a ten year period.[101] The fact that quadriceps strength of the non-surgical side of the THA group was higher pre-operatively compared to the control group, may also indicate that the current THA group is likely stronger than the control group.

Before surgery, the patients included in this study were significantly impaired in terms of pain and functional performance. Following the surgery, patients experienced important reduction of pain and improvement in both self-reported measures of function, hip joint range of motion and functional performance, which is similar to previous studies on the recovery of patients after THA.[75,77,80,85,102] Several measure of impairments, such as strength and range of motion, as well as functional performance continued to improve between three and twelve months after the surgery. The third month post-surgery represent a clinical milestone as patients are usually discharged from routine orthopedic care. However, patients may still have the potential to improve and this may justify the development of targeted intervention that are carried out after discharge from rehabilitation. These type of intervention may also be extremely beneficial and effective as patients do not have to follow surgical precautions to reduce the risk of dislocation.[98]

Limitations

The current study had strict inclusion and exclusion criteria and the results may not be generalized to the population of patients after THA. Patients excluded due to missing data from one or more evaluation time points may have different level of impairments than the patients included in this analysis. The small change in pain, hip ROM, and abductor strength from 3 to 12 months following the surgery likely had a negatively impact on the regression model for hypothesis 3.5.

Conclusion

In conclusion the recovery of patient after THA is not optimal in respect to biomechanical and functional outcomes. Important weakness in the hip abductor

persists as well as limitation in functional performance. While biomechanical abnormality in the sagittal plane appear to resolve after surgery, excessive trunk lean and pelvis drop angle persist up to 12 months following the surgery.

Chapter 4

FEASIBILITY AND PRELIMINARY EFFECTIVENESS OF A SIX-WEEK STRUCTURED EXERCISE AND EDUCATIONAL PROGRAM ON FUNCTIONAL PERFORMANCE AND GAIT BIOMECHANICS IN SUBJECTS AFTER TOTAL HIP ARTHROPLASTY: A CASE SERIES.

Introduction

The incidence of total hip arthroplasty (THA) has been steadily increasing over the past 10 years.[2,3] Although this procedure improves pain and patients perception of functional abilities,[74–76] patients continue to exhibit long lasting impairment and functional limitation compared to older adults without joint pathology.[77,80] This may increase the socio-economic burden of the disease as a higher proportion of younger adults (age between 40 and 65) is undergoing this procedure.[8] Younger individuals may have different functional and participation goals compared to older adults, which may require modification of current rehabilitation protocols with the goal of optimizing the outcomes of the surgery.

The post-operative care of patients after THA is not well defined. Specifically, no standard guidelines exist regarding outpatient physical therapy and there are no strong prospective, randomized trials to evaluate the most effective protocol or timing of rehabilitation after discharge from the hospital.[100,103–105] A survey of 14 high volume orthopedic centers in the United Kingdom indicated that outpatient physical therapy was not one of the routine pathways of care for patients after THA.[99] To date, physical therapy recommendations are hospital- and surgeon-specific.

Underutilization of post-operative rehabilitation may in part explain the residual impairments and deficits measured in this population.[77]

Data from one observational study[77] indicates that patients sustain significant decrease of lower leg strength and functional performance in the first month after the surgery. These authors concluded:

> "The presence of early strength loss supports the need for early rehabilitation intervention to remediate strength losses to optimize recovery beyond levels seen preoperatively. This may require increasing the frequency and intensity of current rehabilitation practices or require more consistent use of rehabilitation after surgery."[77]

Early physical therapy interventions and progressive strengthening exercises have been successful in optimizing outcome after other orthopaedic surgical procedures,[10,11] but they may not be as successful in a post-THA population. These patients usually have movement restrictions and precautions for at least 6-weeks after the surgery to reduce the risk of dislocation. Although the restriction paradigm has been recently challenged, it is well accepted in the surgical community.[106] Therefore, patients who enroll in outpatient physical therapy with hip precautions may not be able to exercise at an intensity level required to promote muscle strength and functional gains. Recent evidence has shown that hip range of motion, muscle function, and physical performance improves between 3- and 12-months after surgery.[80] Rehabilitation interventions during the later recovery period may have an additive benefit.

Current rehabilitation protocols do not typically target physical activity and promote exercise participation. This is concerning as many patients after THA have low levels of physical activity,[107,108] greater risk of weight gain[109,110] and cardiovascular disease. An individual and transitional exercise program during the late phase of recovery is needed to restore normal physical activity levels and overall

health after THA. Similar exercise intervention have been proven beneficial in improving pain and function patients with osteoarthritis,[111] but have not been tested in a population after THA. Interventions after THA may prove more effective because pain, the major barrier to exercise,[112] is often resolved after the surgery.

Several hypothesis were made:

- Hypothesis 4.1. Patients enrolled in the exercise program will participate in at least 90% of the sessions without reporting adverse effects related to the intervention.
- Hypothesis 4.2. At the end of the exercise program, individuals will walk farther distance in the 6MW and have higher hip abductor and quadriceps strength compared to baseline.
- Hypothesis 4.3. At the end of the exercise program, individuals will have more symmetrical vertical ground reaction force during sit to stand compared to the beginning of the exercise.
- Hypothesis 4.4. At the end of the exercise program, individuals will report higher activity level compared to baseline.

Methods

Participants

To be included in the study, participants had to meet the following criteria:

1. Between 40 and 70 years of age
2. Underwent unilateral THA;
3. Between the third and ninth month post-surgery
4. Discharged from standard physical therapy intervention.

Participants were excluded if they had:

5. Neurological, vascular or other lower extremity musculoskeletal conditions that affected gait or functional performance

6. History of chest pain, heart attack, or heart failure
7. History of complication after the THA surgery
8. Uncontrolled hypertension
9. Self-reported lack of sensation in the foot or lower extremity
10. History of cancer in the lower extremity
11. Underwent a revision joint replacement
12. Underwent a previous THA or are planning a contralateral THA within six-months
13. Have any other condition that prevented from exercising on a regular basis

Participants gave informed consent before starting any component of the protocol. The testing and intervention protocol were approved by the Human Subjects Review Board of the University of Delaware.

Intervention

Participants were enrolled in 18 supervised exercise sessions over the course of six-weeks. Each session lasted one-hour and included two 15 minutes aerobic components, one 20 minute strengthening component, and 10 total minutes of recovery and transfer between exercises. This exercise construct has been successfully and safely implemented in the IDEA trial.[111] Methods of aerobic and resistive weight training were tailored to each participant's baseline status and goals, as described in the patient specific functional scale (PSFS). For aerobic exercises, a heart rate monitor was used to confirm that exercise intensity ranged between 65–80% of the predicted hearth rate maximum. The starting intensity and progression of the intervention components were dependent on the individual's tolerance to each exercise session. Before each exercise session, a custom made questionnaire was used to monitor for

current level of pain in the low back and lower extremity joints, and appearance of severe pain, swelling, and tenderness after the previous exercise session. At the end of the session, participants were asked to rate their current level of pain in the low back and lower extremity joints. These data were then used for the feasibility analysis. If any ACSM indication for exercise termination[113] arose during any component of the intervention, the session was immediately terminated.

Participants also met with a health coach during the first week of the exercise intervention. This one-to-one meeting lasted approximately 60 minutes and focused on awareness of healthy eating habits, barriers to participation, personal health goals, and strategies to stay engaged in the program on an individual level. The health coach followed-up weekly through phone calls with each participant to review exercise participation, answer questions, set new goals and provide further information on possible lifestyle adjustments to promote exercise participation. In addition, the health coach provided participants with a FitBit© activity monitor. This small and cheap device gave participants information of their activity measured as steps per day. The FitBit© is easy to use and has a simple interface that can be easily synchronized with smartphones and personal computer. This device was used to engage participants and provide subjects with feedback on their activity level throughout the intervention.

Procedure

Graded Exercise Testing

Prior to inclusion into the study, participants underwent a screening visit and a graded exercise stress test. During the screening, participants' medical history was reviewed by a Board Certified Nurse Practitioner to check for contraindications prior

to the graded exercise test. If no absolute or relative risks were indicated in the initial health history questionnaire,[113] participants were equipped with 10 electrocardiogram (ECG) electrodes and a blood pressure cuff to obtain a baseline resting ECG and blood pressures. If medical history, resting ECG, and resting blood pressure were observed to have no absolute or relative contraindications, participants executed a graded exercise testing according to the Bruce-modified protocol.[114] The graded exercise test applied an initial 25 watts resistance and was increase by 25 watts every 2 minutes until participants reached maximal effort, failed to maintain 60 revolutions per minute, had abnormal symptoms, or asked to terminate the exercise.[113,114] Test was considered valid if participants reached at least 85% of their age predicted maximum heart rate and exercise duration was greater than six minutes.[115] After the test, the results of the graded exercise test were reviewed by a cardiologist to determine if participants were eligible to enroll in the exercise intervention.

If eligible participants were scheduled for the baseline functional and biomechanical testing sessions. If not eligible, participants were encourage to seek medical care and were dropped from the study.

Functional evaluation

The functional evaluation consisted of a battery of self-reported measure of function and activity level, impairment based measures, and performance based tests.

Patients completed the Hip Harris Score (HHS), which is a valid and reliable scale that have been used extensively to evaluate outcomes of patients following THA surgery.[88] This questionnaire ask patients to self-rate their symptoms and dysfunctional related to their hip pathology. Furthermore, it includes some impairment measures, such as presence of contracture and hip range of motion, which are assessed

by the clinician who administered the scale. The total possible score is 100, which represent absence of limitations.

Participants completed the Hip Outcome Survey,[89] which includes six questions that ask patients to rate the effect of six common knee symptoms on daily activity. Patients are asked to rate their symptoms from “I do not have the symptom” to “The symptom prevents me from all daily activity”. In addition, the questionnaire includes seven questions where patients are asked to rate their functional limitations during several different daily activities. Possible answers range from “Activity is not difficult” to “I am unable to do the activity”. Score are assigned to each answer on a 6 point scale from 5 (maximum score) to 0 (minimum score). Total score is presented as percentage with 100% representing full knee function.

Participants completed the Barriers Self-Efficacy Scale (BARSE) questionnaire,[116] which is a 13-item questionnaire that measure participants’ perceived abilities to exercise three time per week for 40 minutes over the next 2 months. For each question participants rated their confidence to execute the behavior from 0 (not at all confident) to 100 (highly confident). Questionnaire score is obtained by summing the confidence rating are then dividing by the total number of item, which makes 100 the maximum total score.

Participants completed the Multidimensional Outcome Expectation for Exercise Scale (MOEES),[117] which is a 15-item questionnaire that evaluate the physical, social, and outcomes expectation domains for exercise. Participants indicated their level of agreement with each question statement on a scale from “1, strongly disagree” to “5, strongly agree”. Each domains is scored separately by summing the

score of response. Higher score indicates higher level of outcome expectations for exercise.

Participants completed the Fatigue Severity Scale (FSS),[118] which is 9-item questionnaire that measure the impact and severity of fatigue and its effect on participants activity and lifestyle. Participants indicated their level of agreement with each question statement on a scale from “1, strongly disagree” to “7, strongly agree”. Maximum score is 63, which indicates higher level of fatigue.

Participants completed the International Physical Activity Questionnaire short form (I-PAQ),[119] which is a questionnaire designed to measure self-reported level of physical activity. The short version of the questionnaire ask participants to report the amount of days and time over the previous week that they spent sitting, walking, and doing vigorous and moderate activities. The metabolic equivalent (MET) energy expenditure over the week can be calculated based on the participants’ answers.

Participants complete the PSFP.[120] In this scale patients are asked to identify activities that they are unable to complete due to their current injury. Participants are then asked to rate their level of impairment related to the activity from “0, unable to perform” to “10, able to perform activity at the same level as before injury”. The minimum detectible change at the 90% confidence interval for a single activity is 3-points. This scale was also used to understand subject-specific exercise goals and to tailor the exercise intervention.

Active-assisted range of motion (ROM) was measured for hip flexion, abduction, adduction, internal rotation, and external rotation as part of the HHS using a goniometer.[59] Subjects were asked to move their limb into end range and the investigator provided support and a slight overpressure. Hip flexion was measured

supine with the knee flexed. Hip abduction and adduction were measured supine with the knee extended. Hip internal and external rotation were measured in a seated position. The total hip ROM was quantified as the sum of all individual range of motions measured in the HHS.

Hip abductor muscle strength was measured during an isometric hip abduction contraction using a hand-held dynamometer (Lafayette Manual Muscle Testing System; Model 01165; Instrument Company, Lafayette, IN).[90] Subjects were positioned in side lying and a non-elastic strap was positioned around the subjects' distal thigh to provide resistance. The hand-held dynamometer was positioned proximal to the lateral femoral condyles and its position was held constant between trials to avoid changes in the resistance moment arm. Subjects were asked to push into the strap (abduct their hip) as hard as possible. The maximal trial from three attempts was used as the maximal isometric contraction. This method has also been shown to be valid and reliable in older adults.[90] Strength values are reported as % of body mass (Kg).

Maximal voluntary isometric strength for the quadriceps muscle was measured using an electromechanical dynamometer (Kin-Com, Chattex Inc., Chattanoga, TN, USA).[33,91] Participants were secured to the dynamometer with the knee positioned at 75° of flexion. Two submaximal contractions (50% and 75%) and one maximal contraction (100%) were completed to familiarize participants with the protocol and to warm-up. After one minute rest, three maximal contractions were performed with one minute of rest between contractions to avoid fatigue. Pain was assessed during isometric strength testing using a 0 to 10 scale where 0 represented no pain and 10 was the worse pain imaginable. Force data were recorded in Newton using a force

transducer located at the distal anterior tibia two centimeters proximal to the lateral malleolus. Data were collected at 200 Hz using custom Labview software (National Instrument, Austin, TX, USA) and normalized according to body mass (Kg).

Participants were also tested using the timed up and go (TUG), the 30-second chair rise test (30SC), the stair climbing time (SCT), and the six-minute walk tests (6MW). For the TUG, participants stood up from a chair without using the armrests, walked as fast as possible for a distance of 3m, turned around, and returned back to sit in the original chair. Time started on the investigator's command and stopped when the participants were fully seated in the chair.[60] For the SCT, participants ascended and descended a set of 12 steps (15cm rise, 20cm run) "as fast as possible while still being safe". If needed, participants were allowed to use one hand-rail, but participants were not allowed to skip steps. The use of handrail and the pattern of stair ascent and descent (step over step or step-to patterns) were recorded. Time started on the investigator's command and stopped when the participants touched the ground with both feet after the last step.[61,62] For the 6MW, participants were asked to walk as far as they could for 6 minutes along a 115 m square hallway. Participants were informed when they reached the second, fourth and fifth minutes. Running was not permitted. Participants were allowed to rest, if needed, but time was not stopped during rest.[61] These tests are recommended to measure performance in older adults with osteoarthritis or after joint replacement.[49]

Biomechanical Testing

Eight infrared cameras (Vicon Motion Systems Ltd, Oxford, UK) were used to detect the position of retro- reflective markers at 120Hz through a collection volume that was approximately 1.2m wide, 1.5m long, and 2.3m high. Sixteen-millimeter

spherical retro-reflective markers were placed bilaterally on the acromion process, iliac crest (aligned vertically with the greater trochanter), greater trochanter, lateral and medial femoral condyle, lateral, and medial malleolus, head of the 1st and 5th metatarsal bone, and two markers on the heel. Rigid thermoplastic shells with four markers were secured bilaterally on the shank, thighs, and upper-back and were used to track the motion of these segments during the dynamic walking trials. Pelvic motion was tracked using a rigid thermoplastic shell with three markers placed below the line between the two posterior superior iliac spines. A standing calibration trial was taken to identify knee and ankle joint centers and create the segment coordinate systems. Functional hip joint centers were determined using a built-in algorithm that calculates the most likely intersection of all axes (effective joint center) and most likely orientation of the axes (effective joint axis) between the pelvis and femur based on a separate dynamic calibration trial in which subjects performed hip flexion, extension, abduction, and circumduction during single leg stance.[92] Joint angles for the ankle, knee, hip, and trunk joints were calculated using Euler X-Y-Z sequence corresponding to sagittal, frontal, and transverse rotations sequence. Two force platforms (Bertec Corporation, Columbus, OH) were embedded into the floor and recorded synchronous ground reaction forces at 1080 Hz. Internal joint moments were calculated and normalized to body mass (kg) * height (m). Joint power were also calculated and normalized by body weight (N).

Participants walked along a 10m walkway at their normal self-selected speed. Participants were shod in their own shoe- wear, but were instructed not to wear sandals for the testing. Self-selected speed was measured during three practice trials prior to data acquisition. Participants completed five successful trials for each leg. A

successful trial was defined as a walking trial that was within 5% of the initial self-selected speed in which at least one foot landed completely within the force plate area and there was no apparent targeting towards the force plate by the participant.

Participants completed three sit-to-stand trials from an adjustable piano stool. Participants were asked to stand near the piano stool so that the height could be adjusted to each participant knee joint line. Subjects were seated in the stool with the trunk in upright position. Feet position was not restricted, but subjects had to maintain each foot on a separate force plate during the test. Subjects were also asked to hold the arms in the lap and to stand from the chair at their self-selected pace but not to turn or look behind for the stool while sitting down. Subjects were allowed to practice the task up to two times. For subject's safety, the stool was secured to the floor with adhesive tape to prevent movement during the task.

Participants completed the step up and over task, which required them to step up and over a wooden step (31.5 cm length, 43.5 cm width, and 20.5 cm height) that was screwed into one force plate via a flat metal footing positioned on each side of the step.[91,121–123] The height of the point of contact of the force plate was then adjusted in the data acquisition software to account for the height of the step. Participants started the motion by standing 5 cm behind the wooden step with their feet shoulder width apart. Participants were instructed to step onto the box with one limb (stepping limb), traverse over the step to clear the swinging limb, land on the force plate in front of the wooden step with the contralateral limb (landing limb), and keep walking. The landing limb did not come to rest on the top of the box. Both limbs were tested and five trials using each limb as the stepping and landing limb were collected. Prior to testing, the step up and over task was described and demonstrated to each participant. Participants

were then asked if they felt they could safely perform the activity. If the answer was no, participants were not allowed to perform the test. If the answer was yes, they were allowed to perform two practice trials. During the practice, the investigator stood close to the participant to assess safety and provide support if needed. After practice, participants were asked again whether they felt confident performing the activity without close supervision. If the answer was "no" or if participants required support from the investigator during the test, they were not allowed to perform the test. Participants were also excluded from the test if the investigator deemed the activity unsafe (i.e., participant lost his or her balance or was not able to perform the task as described by the investigator).

Data Analysis

Walking Trials

Biomechanical variables collected during gait included: peak hip flexion and peak hip extension angles and moments; peak hip adduction angle and moment; peak trunk lean; and peak pelvis drop. Frontal plane trunk rotation in the lab coordinate system was measured to remove the effect of altered pelvis position on the trunk angle calculation. This was calculated as the trunk angle in the plane perpendicular to the walking direction and represents what is clinically referred to as trunk lean. Peak lateral trunk lean in the lab coordinate system was calculated as the maximum trunk lean angle towards the stance side. Positive values indicate lateral trunk lean toward the stance side for both trunk angle and lateral trunk lean.

Pelvic drop was also evaluated by measuring the rotation of the pelvis in the lab coordinate system. This angle was calculated as the angle of the pelvis segment

about an axis parallel to the direction of walking. This conveys information of the frontal plane pelvis rotation, irrespective of the position of the femur segment. This was defined in this paper as pelvis rotation. Negative values indicate rotation in which the contralateral iliac crest is depressed relative to the hip (akin to hip adduction).

This data were calculated during the stance phase of gait on the surgical leg and were normalized according to 100% of stance.

Sit to stand trials

The sit to stand trials were divided into three functional intervals: rising, which was the interval in which participants stood from the stool; standing, which was the interval in which participants maintained a steady stance position; and return to sit, which was the interval in which participants returned to a sitting position. Only the data from the rising portion of the task were used for the analysis. The start of the sit up interval was based on the acceleration of a marker placed on the acromion: when the acceleration exceeded $0.1 m/s^2$ a "start" event was created.[124] The end of the sit up interval was based on the vertical position a marker placed on the acromion: when the marker reached a maximum in height an "end" event was created.[124] The peak vertical ground reaction force (vGRF) was calculated for each leg during the sit up interval. This inform us of the weight distribution during the task. The symmetry index of vGRF was then calculated by dividing the value measured under the surgical side by the non-surgical side.

Step up and over trials

The data of the stance phase for the stepping and landing limb were time normalized to 100% of stance for each limb. The time series curves for the stepping

and landing limb were visually inspected to check for consistency during landing. The task was divided into functional intervals. The stepping portion of the task was divided in two intervals: 1) from initial contact on the box to the highest position of a marker placed on the pelvis, which is the time at which the stepping limb generated energy to propel the center of mass up onto the step (propulsive phase); and 2) from the heights position of the pelvis marker to toe-off from the box, which is the time at which the stepping limb absorbed energy during the descent of the center of mass (lowering phase).[91] For the landing limb, only one phase was evaluated; this was the interval between initial contact and 25% of stance and was considered the weight acceptance phase. During this interval, the landing limb provides a stable support for the level transition and contributes to absorbing the energy generated during the descent of the center of mass.[91]

Variable of interest included peak hip flexion, extension, and adduction angle; peak hip flexor, extensor, and abduction moment; peak power generation and absorption; peak trunk lean; and pelvis drop. These variables were calculated during the propulsive and lowering phase executed with the surgical limb.

Statistical analysis

Due to the nature of the study and the limited sample size only descriptive statistics were calculated. For each functional and biomechanical measures, percentage increase/decrease from the baseline time point were calculated.

Results

Participants

Two participants were recruited for this case series. Both participants underwent unilateral THA due to hip osteoarthritis from the same experienced surgeon with an anterolateral approach. Pre-operative characteristics of the participants are reported in table 11.

Table 11 Pre-operative characteristics of the sample

	Case A	Case B
Gender	Female	Male
Age, years	61	61
Height, m	1.55	1.86
Weight, kg	55	109
BMI, kg*m2	22.89	31.51
HOS, %	39.47	71.05
HHS, %	54	63
Hip SX, [0-10]	7	3
Knee SX, [0-10]	8	1
Hip NSX, [0-10]	0	0
Knee NSX, [0-10]	0	0
Low Back, [0-10]	0	0
TUG, s	6.11	5.11
SCT, s	12.3	9.11
6MW, m	435.2	523.69
Hip strength SX, % Body mass	0.16	0.11
Hip strength NSX, % Body mass	0.16	0.25
Knee strength SX, Nm/Kg	0.75	1.73
Knee strength NSX, Nm/Kg	1.18	1.89

Case A

A 62 year old female was recruited approximately 7 months after her THA surgery. She underwent 4 acute care physical therapy sessions while hospitalized. After discharge, she was enrolled in 12 outpatient physical therapy sessions. She reported sustaining a fall approximately four months after the surgery and fracturing her wrist, but her past medical history was otherwise non-significant. At the time of enrollment, the wrist cast was removed and she was cleared by her doctor to return to activity.

Case B

A 62 year old male was recruited approximately 8 months after his THA. He underwent 3 acute care physical therapy sessions while hospitalized. After discharge, he was enrolled in 5 home and 12 outpatient physical therapy sessions. The past medical history was non-significant, although the baseline graded exercises testing session was terminated due to presence of ectopic hearth beats in the resting ECG. This required the participant to obtain clearance from his cardiologist before undergoing the stress test. After clearance was obtained, he was able to complete the graded exercise testing and was enrolled in the study.

Feasibility analysis

Both patients completed all 18 exercise testing sessions. Exercise log for the first, ninth, and eighteenth exercise session are reported in appendix A (case A) and appendix B (case B). Case A reported one episode of severe pain in the operated hip joint that developed after the eighth exercise session (table 12). However, pain resolved within few minutes and patient did not report hip pain immediately prior to or during the ninth exercise session. Case A reported low back pain at the beginning of

most exercise sessions; however, the pain decreased or did not change at the end of each session.

Table 12 Self-reported severe joint pain, swelling, tenderness, and pain level for case A during each exercise sessions.

		Before exercise session								**After exercise session**				
		After last exercise session			Pain level					Pain level				
	Session	Severe joint pain	Joint swelling	Joint tenderness	Hip SX	Knee SX	Hip NSX	Knee NSX	Low Back	Hip SX	Knee SX	Hip NSX	Knee NSX	Low Back
Case A	#1	NA								0	0	0	0	0
	#2	No	No	No	0	0	0	0	3	0	0	0	0	0
	#3	No	No	No	0	0	0	0	3	0	0	0	0	1
	#4	No	No	No	0	0	0	0	2	0	0	0	0	1
	#5	No	No	No	0	0	0	0	1	0	0	0	0	1
	#6	No	No	No	0	0	0	0	2	0	0	0	0	1
	#7	No	No	No	0	0	0	0	2	0	0	0	0	0
	#8	Yes[a]	No	No	0	0	0	0	1	0	0	0	0	0
	#9	No	No	No	0	0	0	0	1	0	0	0	0	1
	#10	No	No	No	0	0	0	0	0	0	0	0	0	1[b]
	#11	No	No	No	0	2	0	0	0	0	0	0	0	1[b]
	#12	No	No	No	0	0	0	0	0	0	0	0	0	0
	#13	No	No	No	0	0	0	0	0	0	0	0	0	0
	#14	No	No	No	0	0	0	0	2	0	0	0	0	0
	#15	No	No	No	0	0	0	0	2	0	0	0	0	0
	#16	No	No	No	0	2	0	0	2	0	0	0	0	0
	#17	No	No	No	0	1	0	0	2	1[b]	1	0	0	1
	#18	No	No	No	1	1	0	0	2	0	0	0	0	1
[a], Episode of groin pain that lasted few minutes.														
[b], Pain developed during the exercise intervention.														

Case B did not report any severe joint pain, swelling, and joint tenderness (table 13). He reported low level pain in the surgical hip after the first two exercise sessions, but this pain did not persist.

Table 13 Self-reported severe joint pain, swelling, tenderness, and pain level for case B during each exercise sessions.

		Before exercise session								**After exercise session**				
		After last exercise session			Pain level					Pain level				
	Session	Severe joint pain	Joint swelling	Joint tenderness	Hip SX	Knee SX	Hip NSX	Knee NSX	Low Back	Hip SX	Knee SX	Hip NSX	Knee NSX	Low Back
Case B	#1	NA								1[a]	0	0	0	0
	#2	No	No	No	0	0	0	0	0	2[a]	0	0	0	0
	#3	No	No	No	0	0	0	0	0	0	0	0	0	0
	#4	No	No	No	0	0	0	0	0	0	0	0	0	0
	#5	No	No	No	0	0	0	0	0	0	0	0	0	0
	#6	No	No	No	0	0	0	0	0	0	0	0	0	0
	#7	No	No	No	0	0	0	0	0	0	0	0	0	0
	#8	No	No	No	0	0	0	0	0	0	0	0	0	0
	#9	No	No	No	0	0	0	0	0	0	0	0	0	0
	#10	No	No	No	0	0	0	0	0	0	0	0	0	0
	#11	No	No	No	0	0	0	0	0	0	0	0	0	0
	#12	No	No	No	0	0	0	0	0	0	0	0	0	0
	#13	No	No	No	0	0	0	0	0	0	0	0	0	0
	#14	No	No	No	0	0	0	0	0	0	0	0	0	0
	#15	No	No	No	0	0	0	0	0	0	0	0	0	0
	#16	No	No	No	0	0	0	0	0	0	0	0	0	0
	#17	No	No	No	0	0	0	0	0	0	0	0	0	0
	#18	No	No	No	0	0	0	0	0	0	0	0	0	0
[a], Pain developed during the exercise intervention.														

Case A

Case A started the intervention with moderate low back pain, which decreased by 60% at the end of the intervention (Table 14). While the HHS score did not change, there was a 14% improvement of HOS score. Only small improvements in SCT and 6MW were measured at the end of the intervention. Both hip abductor and quadriceps strength on the operated side increased approximately 30% from baseline. However, only quadriceps strength reached a level similar to the non-operated side by the end of the intervention (symmetry index = 96%). BARSE score improved 71%, while the social and self-evaluative outcome expectation for exercise domains of the MOEES questionnaire improved 31 and 14%, respectively. The FSS score at the end of the intervention was 22% lower compared to baseline. Important improvements were seen in the IPAQ score which increased to 12558 MET/week from 2838 MET/week. Furthermore, the participant reported improvement in the PSFS, which reached a level of 10 for all activities reported.

Case B

A 5% reduction of body weight was found at the end of the intervention. Case B reported mild pain at both knees and low back prior to the intervention, which was resolved at the end of the intervention. HOS and HHS score improved of ~3 and 8% respectively. There were no meaningful improvements in performance-based tests of function. Hip abductor and knee strength on the operated side improved 22 and 31%, respectively. No change in hip abductor strength were measured on the non-surgical side, while quadriceps strength of the non-surgical side decreased 16% at the end of the intervention. An 18% decrease on the BARSE score was measured at the end of

the intervention. The social outcome expectation for exercise domain of the MOEES questionnaire improved 33% from baseline. IPAQ score improved from 891 MET/week to 4759.5 MET/week. FSS score decreased 41%. The participant reported improvement in the PSFS, which reached a level of 9 for golfing and 7 for running.

Table 14 Percentage change of self-reported, impairment-based, and performance-based measures from baseline to the end of the intervention (6 weeks).

		Case A			Case B		
		Baseline	6wks	% change	Baseline	6wks	% change
Weight, Kg		55	54	-2	108	103	-5
BMI, kg*m2		22.89	22.47	-2	31.49	29.77	-5
Hip SX, [0-10]		1	1	0	0	0	0
Knee SX, [0-10]		0	1	100	2	0	-100
Hip NSX, [0-10]		0	0	0	0	0	0
Knee NSX, [0-10]		0	0	0	2	0	-100
Low Back, [0-10]		5	2	-60	2	0	-100
HOS, %		87.5	100	14	97.36	100	3
HHS, %		97	96	-1	93	100	8
TUG, s		4.94	4.96	0	4.43	4.43	0
SCT, s		9.82	8.92	-9	7.63	7.47	-2
6MW, m		636.42	664.6	4	688.23	690.8	0
Hip strength SX, % Body mass		0.14	0.18	29	0.09	0.11	22
Hip strength NSX, % Body mass		0.23	0.27	17	0.26	0.25	-4
Knee strength SX, Nm/Kg		1.9	2.47	30	1.67	2.19	31
Knee strength NSX, Nm/Kg		2.18	2.56	17	2.05	1.73	-16
Hip range of motion							
	Flexion	120	120	0	120	110	-8
	Abduction	15	25	67	15	25	67
	Adduction	20	29	45	11	15	36
	External rotation	25	29	16	43	43	0
	Internal rotation	33	33	0	33	32	-3

BARSE, %		41	70	71	93	76	-18
IPAQ, MET		2838	12558	342	891	4759.5	434
MOOES							
	Physical outcome	29	30	3	29	29	0
	Social outcome	13	17	31	12	16	33
	Self-evaluative outcome	22	25	14	25	24	-4
FFS, [0-63]		32	25	-22	43	23	-47
PSFS, [0-10]							
	Walking long distances	7	10	43	NA		
	Walking upstairs	5	10	100			
	Hiking uphill	4	10	150			
	Fast walking	5	10	100			
	Golf	NA			6	9	50
	Running				4	7	75

Biomechanical data

Case A

Time series curves for the biomechanical variable are reported in figure 6 (gait) and 7 (step up and over).

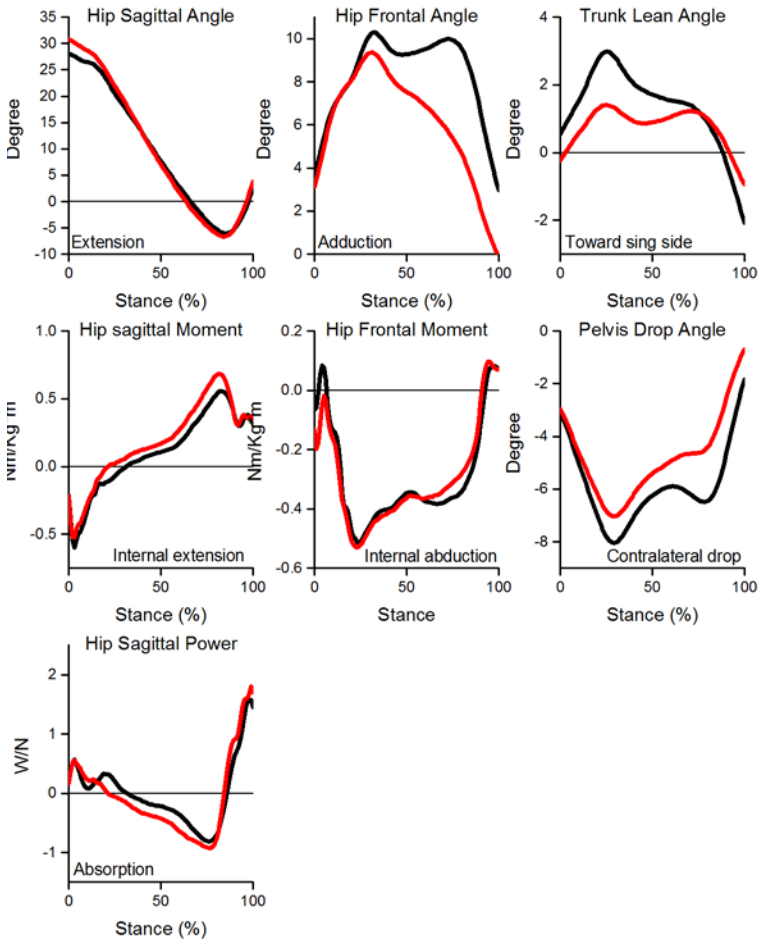

Figure 6 Case A time series curve for the baseline (black line) and post-intervention (red line) biomechanical variables of the surgical limb during gait.

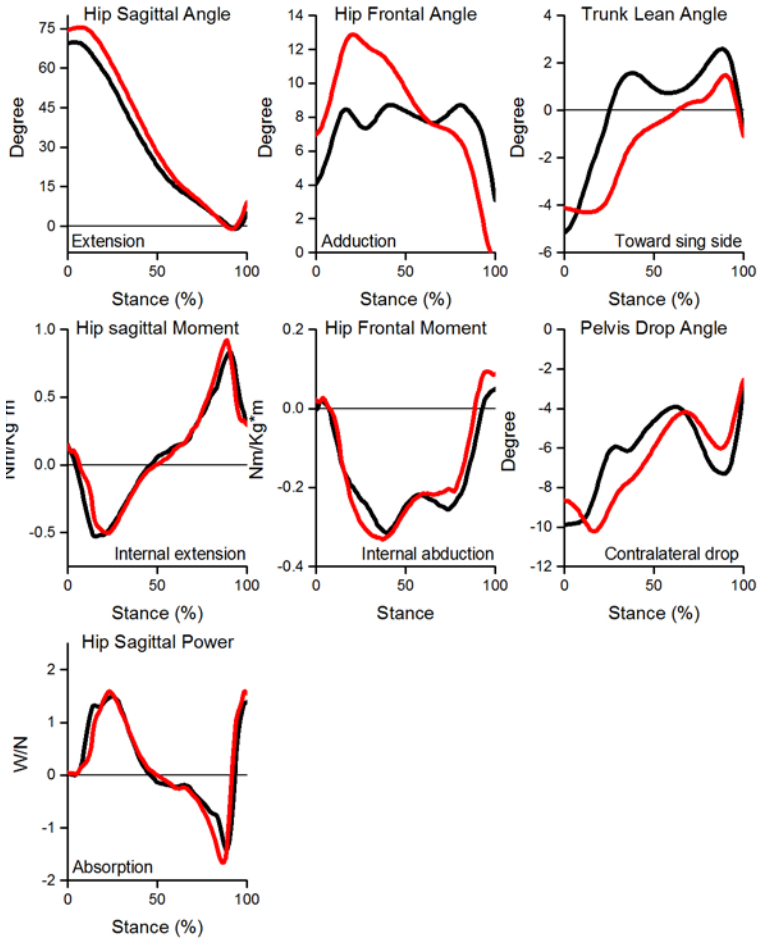

Figure 7 Case A time series curve for the baseline (black line) and post-intervention (red line) biomechanical variables of the surgical limb during the step up and over task.

Greater peak hip flexion angle during both gait and step up and over were measured at the end of the intervention (9 and 8%, respectively, table 15). During both activities, hip internal flexion moment increased approximately 24% (gait) and 10% (step up and over). Power generation and absorption increased during both task. There was a mild reduction in trunk lean and pelvis drop during gait.

Table 15 Biomechanical discrete variables for case A.

	Case A					
	Gait			Step Up and Over		
	Baseline	Six Weeks	% change	Baseline	Six Weeks	% change
Peak hip flexion, °	28.15	30.79	9	69.84	75.56	8
Peak hip extension, °	-6.01	-6.65	11	-0.99	-0.93	-6
Peak hip adduction, °	10.29	9.37	-9	8.72	12.83	47
Peak hip flexion moment, Nm/Kg*m	0.55	0.68	24	0.83	0.91	10
Peak hip abductor moment, Nm/Kg*m	-0.51	-0.53	4	-0.31	-0.33	6
Peak hip power absorption, W/N	-0.81	-0.92	14	-1.41	-1.66	18
Peak hip power generation, W/N	1.57	1.79	14	1.49	1.59	7
Peak trunk lean, °	2.98	1.40	-53	1.57	-0.61	-139
Peak pelvis drop, °	-3.10	-2.96	-5	-4.64	-5.97	29

At the end of the intervention Casa A completed the sit to stand task with symmetrical peak vGRF (Figure 8).

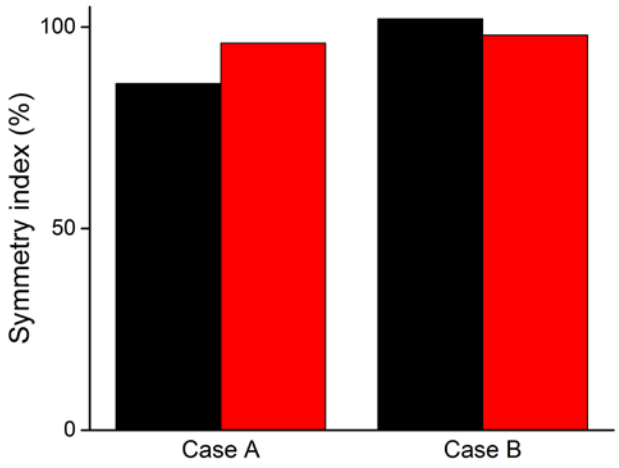

Figure 8 Symmetry index (surgical/non-surgical limb) of vertical ground reaction force during sit to stand. Black bars represent baseline measures and red bars represent end of the intervention measures.

Case B

Time series curves for the biomechanical variable are reported in figure 9 (gait) and 10 (step up and over).

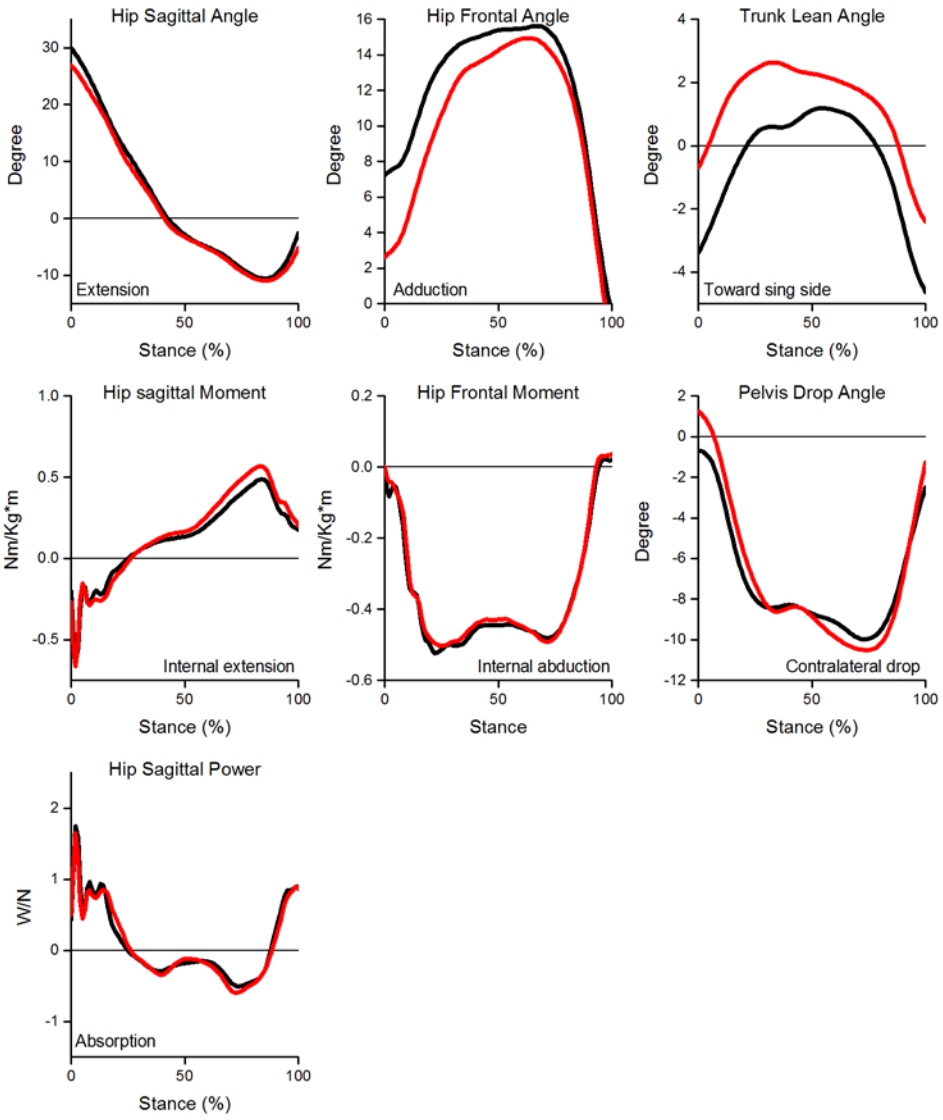

Figure 9 Case B time series curve for the baseline (black line) and post-intervention (red line) biomechanical variables of the surgical limb during gait

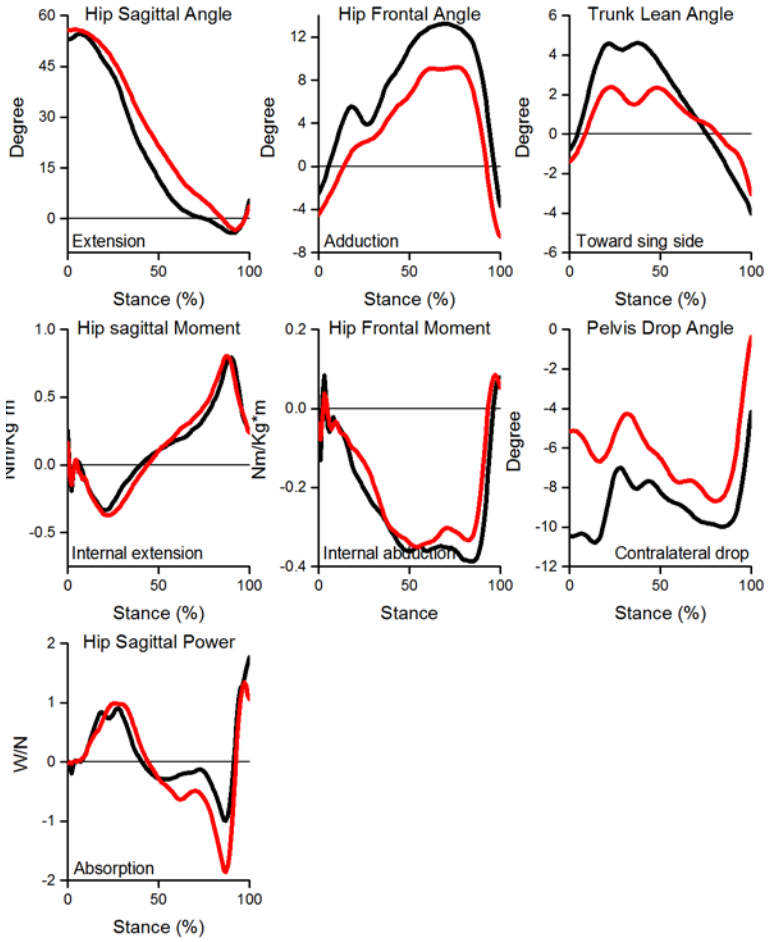

Figure 10 Case B time series curve for the baseline (black line) and post-intervention (red line) biomechanical variables of the surgical limb during the step up and over task.

There was a mild reduction in hip adduction angle, especially during the step up and over task for case B (table 16). Hip flexor moment during gait increased 17%. Hip power absorption increased 18 and 87% during gait and step up and over respectively.

Table 16 Biomechanical discrete variables for case B.

	Case B					
	Gait			Step Up and Over		
	Baseline	Six Weeks	% change	Baseline	Six Weeks	% change
Peak hip flexion, °	29.92	26.98	-10	54.53	55.83	2
Peak hip extension, °	-10.46	-10.92	4	-4.17	-3.25	-22
Peak hip adduction, °	15.38	14.25	-7	11.06	6.62	-40
Peak hip flexion moment, Nm/Kg*m	0.48	0.56	17	0.79	0.80	1
Peak hip abductor moment, Nm/Kg*m	-0.52	-0.50	-4	-0.36	-0.33	-8
Peak hip power absorption, W/N	-0.50	-0.59	18	-0.99	-1.85	87
Peak hip power generation, W/N	1.74	1.64	-6	1.76	1.33	-24
Peak trunk lean, °	1.12	2.63	135	4.60	2.37	-48
Peak pelvis drop, °	-0.70	1.24	-277	-7.00	-4.26	-39

Discussion

The results of this case series demonstrate that an exercise intervention aimed to improve cardiovascular fitness, strength, and activity level in patients at least three months after THA is safe, feasible, and well tolerated. Both participants attended all 18 exercise sessions and no session was terminated or cancelled due to insurgence of symptoms. There was only one reported occurrence of severe joint pain that developed after an exercise session (table 12). However, the participant reported that the pain resolved after few minutes and did not report any pain at the start of the next exercise session. Furthermore, pain in the surgical hip at the end of an exercise session was reported only a total of three times and was limited to minimal pain. Case A reported pain (1 out of 10) after the 17^{th} session, which may be related to the higher level of

exercises. This pain was minimal and disappeared by the following exercise session. Case B reported pain after the first and second session (1 and 2 out of 10, respectively), which may be related to the beginning of an exercise routine. Assessing pain and potential exercise adverse effects (severe pain, joint swelling, and tenderness) may help clinician tailoring exercise session that promote gains, while limiting patients' discomfort.

Joint pain is a common complaint of older adults, and exercise interventions have been proven beneficial to reduce pain associated with low back[125] and lower extremity joint.[126] THA surgery resolved the hip pain associated with the osteoarthritic disease, but both cases enrolled in the exercise intervention with low to moderate pain in different joints: case A reported moderate pain (5/10) in the low back; case B reported low pain (2/10) in both knees and low back. At the end of the intervention, both cases reported reduction of their pain symptoms, which supports the evidence on the effectiveness of exercise interventions to improve low to moderate joint pain.

At the beginning of the intervention both cases had asymmetrical strength for both abductor and quadriceps muscles, with the non-operated side having greater strength. At the end of the intervention, hip abductor and quadriceps strength on the surgical side improved between 22 and 31%. Quadriceps strength symmetry was close to restored at the end of the intervention, but abductor strength asymmetries were still present, despite specific hip abductor strengthening exercises in both open and close chain. Abductor strength gains in the operated side may be limited by the anterolateral surgical approach, which expose patients to higher risk of direct cut of the gluteus medius and the superior gluteal nerve.[97] Downing et al.[127] reported similar isometric hip abductor strength improvements at three and twelve months in patients that

underwent lateral or posterior approach THA surgery. However, the lack of randomization and strength normalization limits the interpretation of the results. Therefore, future study with stronger methodology are needed to measure the effect of surgical approach on functional recovery.

No meaningful change of performance tests were measured at the end of the intervention. However, the participants included in this case series may represent the highest functioning cohort of patients after THA, considering that their performance at the start of the intervention exceeded the average of older adults without joint pathology (data reported in Table 6#, second chapter). However, important changes were observed in the PSFS that exceeded the minimal detectable change for the scale.[120] This intervention may be effective in promoting improvements of patients' specific activities that includes high level of recreational activities (hiking uphill) and sports (golf). Improvements in recreational and sport activities that are meaningful to the patients may also foster improvements in overall activity level, as suggested by the increase of the IPAQ questionnaire score. Restoring participation in higher level of functional activities is paramount and it may be extremely beneficial especially for younger patients. Common reasons to stop exercising after joint replacement are fear of re-injury and fatigue.[128] While this intervention did not specifically addressed "fear of re-injury", both the behavioral component (health coach) and exercise sessions may have changed the patients' perception on barriers that limit the ability to exercise. Patients with high level of barriers perception may get more benefit from this type of intervention. Both cases reported lower perception of fatigue, which, paired with increased physical activity, may indicate that the intervention improved cardiovascular fitness and endurance. Taken together, these results may suggest that the intervention

promoted the resumption of a more active lifestyle. This may in turn promote weight loss in patients that are obese or overweight: at the end of the intervention case B experienced a 5% reduction of body weight, which is considered a clinically meaningful weight loss.[129]

Changes in biomechanics were more variable between the two cases. No changes were observed in relation to trunk lean and pelvis drop angle during gait. These abnormal movement patterns are present before surgery,[85] and may not resolve without specific training. Common positive trends observed at the end of the intervention included higher movement speed and greater peak of internal hip flexor moment during both gait and step up and over task; and greater hip flexion angle and hip power generation and absorption during the propulsive and lowering phase of the step up and over. These changes may indicates higher dynamic functioning of the hip joint. Patients who present with asymmetrical weight distribution during sit to stand may also benefit from this intervention and potentially restore symmetrical performance.

Consideration for future interventions

Patients after total hip arthroplasty tend to overestimate their activity level.[107] Therefore, obtaining a more unbiased measure activity level (i.e., accelerometer) is needed to fully understand whether this intervention truly changes activity level in this population. Adding feedback exercises may optimize outcomes for patients who enroll in the intervention with important movement asymmetries. The proper “dosage” of supervised sessions should also be assessed, especially in relation to the current healthcare marker. Reducing the number of supervised session may be useful to

reduce the cost associated with the intervention or increase the duration of the intervention, without altering outcomes.

Conclusion

This current exercise intervention protocol was well tolerated and did not have negative effect in two patients after THA. Even in highly functioning patients, the intervention was effective to increase: level of ability to complete highly functional recreational and sport related activities; weekly physical activity; and lower leg strength (although hip abductors on the surgical side did not reach a level of performance similar to the non-surgical side). This intervention may be even more beneficial for patients with a greater level of impairments. This intervention offers a novel approach that could potentially restore recreational activity participation, increase level of activity, and promote weight loss in obese and overweight patients after THA.

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Appendix A

DATABASE SEARCH STRATEGIES

Medline

1. Exercise (MESH EXP and MJ)
2. Rehabilitation (MESH EXP and MJ)
3. Physical therapy modalities (MESH EXP and MJ)
4. Physical therapy specialty (MESH EXP and MJ)
5. Exercise Therapy (MESH EXP and MJ)
6. Exercise (TI and AB)
7. Rehabilitation (TI and AB)
8. Physical therapy (TI and AB)
9. Physiotherapy (TI and AB)
10. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. Knee (MESH EXP and MJ)
12. Knee joint (MESH EXP and MJ)
13. Knee (TI and AB)
14. #11 or #12 or #13
15. Knee prosthesis (MESH EXP and MJ)
16. Arthroplasty, replacement, knee (MESH EXP and MJ)
17. Knee arthroplasty (TI and AB)

18. Knee replacement (TI and AB)
19. #15 OR #16 OR #17 OR #18
20. #14 AND #19
21. #10 AND #20

Cinhal

1. Exercise (MJ)
2. Rehabilitation (MJ)
3. Physical therapy (MJ)
4. Exercise therapy (MJ)
5. Physiotherapy (MJ)
6. Exercise (TI or AB)
7. Rehabilitation (TI or AB)
8. Physical therapy (TI or AB)
9. Physiotherapy (TI or AB)
10. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. Knee (MJ)
12. Knee joint (MJ)
13. Knee (TI or AB)
14. S11 OR S13 OR S12
15. Knee replacement (MJ)
16. Knee arthroplasty (MJ)
17. Knee replacement (TI or AB)
18. Knee arthroplasty (TI or AB)

19. #15 OR #16 OR#S17 OR #18
20. #14 AND #19
21. #10 AND #20

Cochrane Library

1. Exercise (MESH EXP)
2. Rehabilitation (MESH EXP)
3. Physical Therapy Modalities (MESH EXP)
4. Exercise therapy (MESH EXP)
5. Exercise (TI, AB, KEY)
6. Rehabilitation (TI, AB, KEY)
7. Physical therapy (TI, AB, KEY)
8. physiotherapy (TI, AB, KEY)
9. exercise therapy (TI, AB, KEY)
10. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. Knee (MESH EXP)
12. Knee joint (MESH EXP)
13. Knee (TI, AB, KEY)
14. #11 or #12 or #13
15. Arthroplasty, replacement, knee (MESH EXP)
16. Knee replacement (TI, AB, KEY)
17. Knee replacement arthroplasty (TI, AB, KEY)
18. Total knee replacement (TI, AB, KEY)
19. Knee arthroplasty (TI, AB, KEY)

20. #15 OR #16 OR #17 OR #18 OR #19
21. #14 AND #20
22. #10 AND #21

Embase

1. Exercise (EXP)
2. Rehabilitation (EXP)
3. Physiotherapy (EXP)
4. Kinesiotherapy (EXP)
5. Exercise (TI and AB)
6. Rehabilitation (TI and AB)
7. Physiotherapy (TI and AB)
8. Physical therapy (TI and AB)
9. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
10. Knee (EXP)
11. Knee (TI and AB)
12. #10 OR #11
13. Knee arthroplasty (EXP)
14. Total knee replacement (EXP)
15. Knee replacement (TI and AB)
16. Total knee replacement (TI and AB)
17. Knee arthroplasty (TI and AB)
18. Total knee arthroplasty (TI and AB)
19. #13 OR #14 OR #15 OR #16 OR #17 OR #18

20. #12 AND #19

21. #9 AND #20

Appendix B

EXERCISE LOG FOR SESSION NUMBER ONE, NINE, AND EIGHTEEN FOR CASE A.

Session		**Mode**	**Distance (m)**	**Parameters**	
#1	Aerobic Session 1	Bike	4570	Resistance: 5; cadence > 60	
	Aerobic Session 2	Elliptical	1432	Resistance: 1; crossramp: 1	
		Exercise	**Session**	**Repetition**	**Resistance**
	Strengthening	Leg press	2	10	10kg
		Bridge with abd rubber band	2	10	green band
		Abductor rise	2	10	green band
		Quadriceps extension	2	10	green band
		Mode	**Distance (m)**	**Parameters**	
#9	Aerobic Session 1	Bike	4570	Resistance: 7; cadence > 60	
	Aerobic Session 2	Elliptical	1609	Resistance: 3; crossramp: 7	
		Exercise	**Session**	**Repetition**	**Resistance**
	Strengthening	Leg press	3	10	20kg
		Abductor rise	3	10	1.5kg
		Single leg step down	3	10	16 cm block; 1kg ball
		Mode	**Distance (m)**	**Parameters**	
#18	Aerobic Session 1	Bike	5648	Resistance:6; cadence > 80	

	Aerobic Session 2	Elliptical	1657	Resistance: 1; crossramp: 1	
		Exercise	**Session**	**Repetition**	**Resistance**
	Strengthening	Single leg bridge	3	10	20kg
		Single leg stance	8	10	Different balance board; 10 ball toss a session
		Single leg step up	3	10	16 cm block with foam pad on top
		Leg curls	3	10	5kg

Appendix C

EXERCISE LOG FOR SESSION NUMBER ONE, NINE, AND EIGHTEEN FOR CASE B.

Session		**Mode**	**Distance (m)**	**Parameters**	
#1	Aerobic Session 1	Treadmill	981	Speed: 2.5; incline: 7.5%	
	Aerobic Session 2	Bike	4618	Resistance 5; cadence > 70	
		Exercise	**Session**	**Repetition**	**Resistance**
	Strengthening	Bridge with abd rubber band	3	10	red band
		Abductor rise	2	10	2.5kg
		Leg extension	3	10	30kg
		Sit ups	3	10	foam pad
Session		**Mode**	**Distance (m)**	**Parameters**	
#9	Aerobic Session 1	Bike	5777	Resistance: 7; cadence > 80	
	Aerobic Session 2	Treadmill	1126	Speed: 2.9; incline: 7.5%	
		Exercise	**Session**	**Repetition**	**Resistance**
	Strengthening	Leg extension	3	10	50kg
		Leg curl	3	10	40kg
		Glut extension	3	10	1.5kg, hold for 5 sec
Session		**Mode**	**Distance (m)**	**Parameters**	
#18	Aerobic Session 1	Treadmill	1335	Speed: 3.4; incline: 6.5%	
	Aerobic Session 2	Bike	5841	Resistance: 5; cadence > 90	
		Exercise	**Sessio**	**Repeti**	**Resistance**

			n	**tion**	
	Strengthening	Golf swing	2	10	5kg ball
			2	10	3kg ball, higher speed
		Ball turn	2	10	5kg ball
			2	10	3kg ball, higher speed
		Golf swing	3	5	Different balance board and BOSU
		Golf put	3	5	Different balance board and BOSU

Appendix D

IRB APPROVAL LETTER FOR AIM 2

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	March 26, 2015
TO:	Lynn Snyder-Mackler, ScD
FROM:	University of Delaware IRB
STUDY TITLE:	[143993-6] Randomized Trial of NMES on Older Adults after Total Knee Arthroplasty
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	Approved for Data Analysis Only
APPROVAL DATE:	March 26, 2015
EXPIRATION DATE:	April 9, 2016
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *(8)*

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

Appendix E

IRB APPROVAL LETTER FOR AIM 3

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	December 8, 2014
TO:	Joseph Zeni, PT PhD
FROM:	University of Delaware IRB
STUDY TITLE:	[291881-20] Biomechanical and Functional Outcomes after Total Hip Arthroplasty
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	December 8, 2014
EXPIRATION DATE:	December 13, 2015
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *(9)*

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

Appendix F

IRB APPROVED INFORMED CONSENT FOR AIM 3

UD IR Approval from 12/08/2014 to 12/13/2015

Project title: Biomechanical and Functional Outcomes after Total Hip Arthroplasty
Principal Investigator: Joseph Zeni PT, PhD
Additional Investigators: Leo Raisis, MD
Gregory Dominick, PhD
Adam Marmon, PhD

Graduate Students: Federico Pozzi
Sumayah Abujaber
Kathleen Madara, PT

You are being asked to participate in a research study that will help describe differences in how people perform functional activities like walking and climbing stairs after having hip replacement surgery. Participation is voluntary. You may withdraw at any time without consequence. A total of 200 subjects will participate in this study. Testing will be completed 2-4 weeks before your surgery, 3 months after your surgery and 1 year after your surgery. All of the testing will take place in the Department of Physical Therapy at the University of Delaware. The research coordinator at the University of Delaware will contact you by phone or mail to schedule your follow-up evaluations.

Testing Procedures

Testing consists of several activities. First, we ask you to complete questionnaires about your ability to perform activities of daily living and exercise. This is followed by strength testing of the muscles of your hip and thigh. We will also evaluate your ability to perform tasks like walking and stair-climbing. This information will help to determine abnormal movement patterns that may lead to problems in other normal activities of daily living. It will teach us about the strength differences between your two legs. Total testing time will take approximately 1.5 hours.

Questionnaires:

You will complete three questionnaires about how your hips are working and your general health. The health history questionnaire is a standard questionnaire that includes questions about your overall physical health. The Hip Outcome Score is a questionnaire that describes how your hip, stiffness and weakness may affect your ability to perform everyday activities. You will also be asked to fill out a questionnaire that asks about your emotional well-being because your emotional state is related to pain. If you have low back pain, you may also be asked to fill out the Oswestry Low Back Disability Index. This asks 10 questions about how the back pain affects your ability to perform daily activities. You will also be asked to complete one questionnaire that asks about your participation in sports and other physical activities. Some of these questions may not apply to you. You can skip any question if it makes you feel uncomfortable or anxious or can skip questions for any other reason without penalty.

Functional Tests:

How far you can bend and straighten both hips will be measured. Functional testing will include four parts. These are a timed walking test, a timed stair-climbing test, a chair

rising test, and a six minute walk test. The timed walking test times how long it takes you to stand up from a chair, walk three meters, turn around and return a seated position in the chair. The chair rising test assesses how many times you can stand up out of a chair in 30 seconds. The stair-climbing test times how long it takes you to walk up and down one flight of stairs. The six minute walk test assesses how far you can walk in 6 minutes.

Strength Testing:

The strength of the muscles on the outside of your thigh will be tested with a hand held device. You will lie on a padded table and asked to push into the device as hard as you can. A second strength test will assess the strength of the muscles on the front of your thigh. You will be seated in a device that will measure the amount of force you can produce. You will be asked to kick as hard as you can. If at any time, discomfort becomes more than you care to tolerate, let us know and we will stop further testing.

Risks

The procedures to which you will be exposed are safe, but you may experience some muscle soreness a day or two following strength testing. This soreness is similar to the muscle soreness that you may feel if you lift weights or vigorously exercise. It is often a sign that you are increasing your muscle strength. Although the force levels used in this study pose very little risk for injury, it is possible that a muscle strain could occur. Because we will be evaluating the way you move during a variety of activities, tripping and falling are risks for the functional evaluations.

Compensation

You will receive a $25 gift card to a local retailer at each testing session. Because there are 3 testing sessions, you will receive 3 gift cards if you complete all of the testing sessions.

Benefits:

The benefits of this study include functional analyses by a licensed physical therapist. This provides you with detailed information about your legs and how you perform the functional tasks. The information that we obtain with our testing will be used to guide future physical therapy treatments. It will also provide doctors and therapists with information about changes in your legs affect your ability to perform everyday activities after surgery.

Confidentiality

Data will be entered from the record to a computerized database where all patients will be identified by a case number. Neither your name nor any identifying information will be used in any publication or presentation resulting from this study. Only you and the investigators will have access to the data. Data will be stored indefinitely. You may reach the investigator at any time, if you have questions or problems associated with the study. The telephone numbers are listed at the end of this form.

What if you are injured during your participation in the study?

If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

Subject Statement

The functional and strength testing session will last up to 90 minutes. I am between the ages of 35 and 85 and do not have:

Hypertension (high blood pressure) that is not controlled by medication
Neurologic impairments (for example, stroke, or head injury)
I am not currently receiving treatment for active cancer

Your signature below indicates that you are voluntarily agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

If you have any questions about this study, please contact the Principal Investigator, Joseph Zeni at 302-831-4263.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

_____ _____ _____

Subject's Signature Date Witness (Signature)

_____

Subject's Name (Printed)

Appendix G

IRB APPROVAL LETTER FOR AIM 4

UNIVERSITY OF DELAWARE
RESEARCH OFFICE
210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE: June 3, 2015

TO: Joseph Zeni, PT, PhD
FROM: University of Delaware IRB

STUDY TITLE: [582379-6] Diet and exercise after total joint replacement

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED
APPROVAL DATE: June 3, 2015
EXPIRATION DATE: April 15, 2016
REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # *(46.110 (b) (2)*

Thank you for your submission of Amendment/Modification materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

Appendix H

IRB APPROVED INFORMED CONSENT FOR AIM 4

UD IRB Approval from 06/03/2015 to 04/15/2016

Project title: Diet and exercise after total joint replacement

Principal Investigator: Joseph Zeni PT, PhD

Other investigators: Adam Marmon, PhD; Gregory Dominick, PhD; Federico Pozzi, MA; Kathleen Madara, DPT; Tara Leonard,

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?
You are being asked to participate in a research study conducted by the Department of Physical Therapy at the University of Delaware. The purpose of this study is to determine if dieting and exercising after total joint (hip or knee) replacement will reduce body weight and improve your ability to perform daily activities, like climbing stairs or walking moderate distances. This study will help us to determine the feasibility of this intervention and refine the aims for a larger clinical trial.

You are being asked to participate in this study because this research project includes patients after total hip or knee replacement. A total of 10 subjects will participate in this six weeks study. 5 subjects will participate in the diet and exercise intervention (Diet and Exercise Group) and 5 subjects will participate in their normal daily routine (Clinician Advice Group).

You will not be able to participate in this study if you:

- Have diagnosed high blood pressure that is not controlled by medication
- Have been diagnosed neurological disorder including stroke, traumatic brain injury, or any other neurological condition that affects decision making or ability to move normally
- History of chest pain (angina), heart attack (myocardial infarction), or heart failure
- Have condition that results in no sensation in the foot or leg
- Had complications after your joint replacement, including:
    - Heart or lung problem that required extended hospital stay
    - Blood clot, also known as deep vein thrombosis or DVT
    - Infection in your operated joint that required additional surgery
- Underwent a revision joint replacement
- Planning to replace any other joint in the lower extremity within 6 months.
- Have any other condition that prevents you from exercising on a regular basis

WHAT WILL YOU BE ASKED TO DO?
First you will be asked to take part in a graded exercises testing session. The results of the

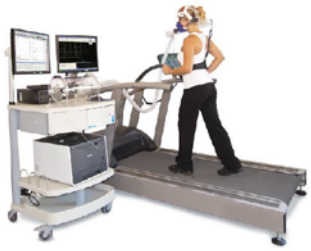
Subjects Initials_____ Page 1 of 8

graded exercise test will then be reviewed by a cardiologist to determine if it is safe for you to participate in the intervention. If you are clear to participate in the intervention, you will then be asked to participate in 1) functional, motion analysis and exercise testing session at baseline session (3 to 9 months after your joint replacement), 2) a six week intervention (either Diet and Exercise group or Clinician Advice group), a 3) functional and motion analysis sessions at the end of the intervention, and 4) a functional testing session 3 months after completing the intervention.

Graded Exercise Testing (Screening Visit; ~ 1.5 hour)

You will also undergo a clinical screening to make sure that you do not have an abnormal response to exercise. This screening visit will be performed at the Nurse Managed Health Care Center (NMHC) at the University of Delaware STAR campus. This will include a medical history screening and measurement of your heart's activity using electrocardiogram (ECG). If your medical history and heart rhythm is normal, you will then perform an exercise stress test on a treadmill or a stationary bicycle. During the exercise test:

- 10 electrodes will be placed on your chest in order to monitor your heart rate and blood pressure during exercise.
- Every 3 minutes the speed and grade of the treadmill or the resistance of the bicycle ergometer will be increased.



The test will be stopped when you reach maximal effort. The test will also be stopped earlier if you have any abnormal symptoms such as chest pain, have an abnormal blood pressure response, have an abnormality on the electrocardiogram, or if you request to stop. It is normal to breathe heavily and sweat during the exercise test. Subjects that had potentially bad changes in their heart rhythm will be referred to cardiologist for follow-up and will not be eligible to participate in the study. This screening visit will take approximately 1.5 hours to complete. The medical screening and resting ECG will take approximately 45 minutes. The graded exercise test will take approximately 45 minutes to complete, although the walking or biking will not take the whole time. Part of the 45 minutes is the set up time for the test.

Physical Activity Monitoring

After finishing the graded exercise testing, you will be given a pedometer to wear for one week. This is a small device that can be worn on a belt around your waist. It measures how many steps you take each day and measures the intensity of your physical activity. This monitor DOES NOT track your location or position. This monitor will be returned at your functional and biomechanical testing session, which will take place one week after your graded exercise test.

Motion analysis (~1.5 hours)

Motion analysis testing will take place one week after the graded exercise testing. Motion analysis

provides information about how you walk, ascend and descend steps, and stand from a chair. Four-inch wide elastic bands will be wrapped around your thighs, calves, and pelvis. Small, reflective markers will be attached. Additional reflective markers will be taped to your sneakers, your ankles, knees and hips with adhesive skin tape. You will be asked to perform up to 10 walking trials, up to 10 trials arising from a chair and returning to sitting, and up to 10 trials ascending and descending a single step. While you are performing these activities, a computer records the motion of the markers attached to your body.

Functional Testing (~ 1 hour)

Functional testing will take place one week after the graded exercise testing. This session consists of questionnaires, functional activities and strength testing. Information about your height, weight, age, sex, and waist circumference will also be recorded. This portion will take approximately 1 hour to complete. This testing will take place at the University of Delaware STAR campus.

Questionnaires: You will complete several questionnaires about how your knees and hips are working and your general health. The Health History questionnaire is a standard questionnaire that includes questions about your overall physical health. The Hip or Knee Outcome Score is a questionnaire that describes how your hip or knee stiffness and weakness may affect your ability to perform everyday activities. The CES-D questionnaire asks about your emotional well-being because your emotional state is related to pain. If you have low back pain, you may also be asked to fill out the Oswestry Low Back Disability Index. This asks 10 questions about how back pain affects your ability to perform daily activities. The Fatigue Severity Scale is a 10 item questionnaire that measures the impact of fatigue on your daily activity. The IPAQ-short form, which is a 4-items questionnaires that measure physical activity level. The Patient-Specific functional scale asks about the goals and outcomes that you would like to achieve or improve. The Barriers-self efficacy (BARSE), which is a 13-items questionnaire that measure barriers to exercise. The Multidimensional Outcome Expectations for Exercise Scale (MOEES), which is a 15-items questionnaire that measure exercises expectation and outcomes. The Diet-self efficacy and Social Support Scale will also be completed, which measures eating habits. Some of these questions may not apply to you. You can skip any question if it makes you feel uncomfortable or anxious or can skip questions for any other reason without penalty.

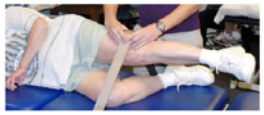
Functional Tests: Functional testing will include four tests. These are a timed walking test, a timed stair- climbing test, a six minute walk test, and a timed chair-rise test. The timed walking test



times how long it takes you to stand up from a chair, walk three meters, turn around and return a seated position in the chair. The stair-climbing test times how long it takes you to walk up and down one flight of stairs. The six minute walk test assesses how far you can walk in 6 minutes. The timed chair-rise test assesses how many times you can get out of a chair and sit back down in 30 seconds without using your hands to push up. How far you can move your hips or knees

will also be measured.

Strength Testing: The strength of the muscles on the outside of your thigh are tested with a hand held device. You will lie on a padded table and asked to push into the device as hard as you can. A second strength test will assess the strength of the muscles on the front of your thigh. You will be seated in a device that will measure the amount of force you can produce. You will be asked to kick as hard as you can. If at any time, discomfort becomes more than you care to tolerate, let us know and we will stop further testing. (Example of hip strength testing shown at right)



Diet and Exercise Training (Diet and Exercise group only)

After completing the Exercise Testing and Functional Testing sessions, half of the subjects (5 people) will be randomly placed in the Diet and Exercise group. If you are randomized in the Diet and Exercise group you will be required to attend: one graded exercise session (baseline) and three motion analysis and functional evaluation sessions (baseline, end of intervention and 3-months follow-up). The time commitment for attending these session will be approximately 10 hours total. Additionally, you will participate in an intervention that involve two meeting with a health coach and 18 exercise sessions. The time commitment for attending these sessions will be approximately 20 hours over a six-week period.

You will exercise in the STAR campus facility 3 times per week for an hour each session. At each of the exercise sessions, a researcher will take your blood pressure and heart rate and before and after exercise. The exercise routine will consist of 15 minutes of aerobic exercise (treadmill, stationary bike, elliptical), 20 minutes of strengthening exercises, 15 more minutes of aerobic exercise, then a 10 minute cool-down period (stretching). During the aerobic exercise, a researcher will assess your heart rate to make sure that the exercise intensity is enough to be between 50–75% of your heart-rate reserve + resting heart rate. The heart-rate reserve is measured during your Graded Exercise Test. The heart-rate reserve is calculated as your (maximal heart rate – resting heart rate). You can think of this as working at 50-75% of your maximal effort during the exercises.

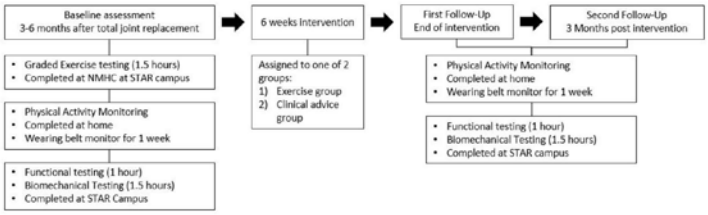
A health coach will also meet with subjects in this group during the first week of the exercise intervention. The exercising will take place at the STAR Campus and the health coaching will take place in the same location or by phone. Subjects in this group will complete a weekly log book to record doctor's visits, pain medication use, changes in joint pain and exercise participation. The health coach will call you once a week to assess barriers to exercises, update goals and answer questions about the weekly log. The health coach will also give you a FitBit activity monitor. This is a small electronic device that sync wireless with your smartphone or personal computer. It measures your daily activity as step count per day. The health coach will use this device to set daily activity goals through the intervention. In addition, this device will give you feedback on your daily activity level. At the end of the intervention, you will be able to keep the FitBit monitor.

Clinician Advice Group

If you are randomized in the Clinical Advice group you will be required to attend: one graded

exercise session (baseline) and three motion analysis and functional evaluation sessions (baseline, end of intervention and 3-months follow-up). The time commitment for attending these session will be approximately 10 hours total.

Subjects in the Clinician Advice group will not participate in any specific exercise or diet interventions. Subjects in this group will perform their normal daily routine for the duration of the study (six weeks). Subjects in this group will also complete the weekly log book to record doctor's visits, pain medication use and changes in joint pain. You will receive a call once a month to answer any questions about the weekly log. After the follow-up testing session (4.5 months after baseline) you will have the opportunity to meet with the health coach to review barriers to exercise and healthy eating habits. You will also receive a complimentary FitBit monitor after your follow-up testing session, which you can then use to measure your activity level. The meeting with the health coach will last approximately 1 hour.



WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There exists the possibility of certain changes occurring during the graded exercise test. These include abnormal blood pressure, fainting, abnormal heart beats, and in rare instances, heart attack, stroke, and death. In order to minimize these risks, an electrocardiogram and blood pressure will be monitored throughout. The test will be immediately stopped if any abnormalities develop. You can stop the test at any time if you have excessive feelings of fatigue or any other discomfort. Shortness of breath is a normal response to exercise testing, and will be experienced during the test.

During motion analysis testing, minor skin irritation may occur from the adhesive tape used to place markers on the skin. Because the testing period is relatively short, this is highly unlikely. Hypoallergenic tape is used to reduce risk. If you have known allergy to adhesive materials, you may choose not to participate. Because we will be evaluating the way you move during a variety of activities, tripping and falling are risks for the motion analysis and functional evaluations.

After functional evaluation, you may experience some muscle soreness for day or two. This soreness is similar to the muscle soreness that you may feel if you lift weights or vigorously exercise. It is often a sign that you are increasing your muscle strength. Although the force levels used in this study pose very little risk for injury, it is possible that a muscle strain could occur. The tests of physical function are similar to activities performed on a daily basis. If you are having difficulty or pain performing any of the tasks let the investigators know and the task will

be stopped or modified.

Subjects in the Diet and Exercise group will also be asked to exercise 3 times per week. This will include aerobic and strengthening exercises, which can lead to muscles soreness within a day or two of exercising.

WHAT ARE THE POTENTIAL BENEFITS?

Potential benefits to the participant: The benefits of this study include functional analyses by a licensed physical therapist. This provides you with detailed information about your legs and how you perform the functional tasks. A letter describing your functional abilities and test scores will be mailed to you after the initial and follow-up testing sessions. In addition, subjects in the diet and exercise group will receive six weeks exercise training during the course of the study at no cost. Exercise training has been shown to improve many health conditions and may also improve your physical status. Subjects in both groups will also receive a FitBit activity monitor, although subjects in the Clinician Advice group will receive it at the conclusion of the study. Cost of a 2 month enrollment in a local fitness center (YMCA) will also be provided for subjects in the Clinician Advice group, although this will occur at the conclusion of the study period. Subjects will also receive a free medical screening and exercise testing before beginning the study at the NMHC.

Potential benefits to society: The results from this study will help us to refine our methods and testing procedures in anticipation of a future, larger study evaluating exercise after total joint replacement. If the results from this and future studies show that exercise is beneficial to persons after total joint replacement, exercise and diet programs may become the standard of care in our facility after joint replacement.

HOW WILL CONFIDENTIALITY BE MAINTAINED?

1. Data from the screening visit at the Nurse Managed Health Center

The NMHC is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected. Per the research protocol the following information from your NMHC medical record will be disclosed and used in the research study:

- Vital Signs & Biometric Measurements (B/P, Height & Weight etc.)
- Electrocardiogram (ECG) recordings and results
- Cardiac Exercise Stress Test recordings and results

The NMHC will not disclose information about your medical history to the researchers.

2. Data from the functional testing and intervention

Data will be entered from the written records (questionnaires, exercise and medical logs, data collection forms) to a computerized database where all patients will be identified by a case number (example: TKA-DE015). Your name will not appear on any computerized item that is

linked to your data and your name will not appear on any written study record. All written documents containing data will be stored in a locked filing cabinet in a locked room. Signed consent forms will not be kept in the same folder as subject data.

All electronic data will be stored on a secure computer server that requires a username and password to access. Any electronic record containing personal information (name, phone number, address, or date of birth) that is linked to your subject number will only be accessible by the research coordinator and primary study investigator. This information will be encrypted and stored on a computer server that requires a username and password to access. Data will be stored indefinitely and may be used in future studies, but any information linking your subject number to your name will be destroyed at the conclusion of the study. Only de-identified data will be used for analysis. You may reach the investigator at any time, if you have questions or problems associated with the study. The telephone numbers are listed at the end of this form. Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?
There are no costs associated with the research, although subjects will be required to arrange their own transportation to and from the testing and exercise sessions.

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?
You will be receive a gift card in the amount of $25 for a local retailer (Starbucks, Barnes and Noble, etc.) for each of the testing sessions. Because there are 4 testing sessions (2 at the baseline evaluations, 1 at the end of the intervention and 1 follow-up evaluation), a total of 4 gift cards will be received for completing all testing sessions. The gift card will be provided at the conclusion of each testing session.

WHAT IF YOU ARE INJURED BECAUSE OF THE STUDY?
If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?
Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the University of Delaware.

Subjects who are enrolled as participants in the Clinician Advice group will not be enrolled in a fitness center and will not receive health or dietary coaching as part of this study. Should subjects

in this group wish to receive these services, they can inform the researcher of this desire at the end of the study period. After the final testing session, the study investigator will offer 2 month enrollment in a YMCA (Wilmington, Bear, or Brandywine), and a health and dietary consultation free of charge. The investigator will facilitate these meetings, which must be completed within one month of completing the study.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?
If you have any questions about this study, please contact the Principal Investigator, Joseph Zeni, Jr. PT PhD at 302-831-4263.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

Your signature below indicates that you are agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep. By signing this consent form, you indicate that you voluntarily agree to participate in this study.

Signature of the participant	Date
Print name of the participant	Witness

Subjects Initials_____

Appendix I

COPYRIGHT RELEASE FORM: RELATIONSHIP BETWEEN BIOMECHANICAL ASYMMETRIES DURING A STEP UP AND OVER TASK AND STAIRCLIMBING AFTER TOTAL KNEE ARTHROPLASTY

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Appendix J

COPYRIGHT RELEASE FORM: SIT-TO-STAND BIOMECHANICS BEFORE AND AFTER TOTAL HIP ARTHROPLASTY

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